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8 Commission

9 None

10 Schering

11 SPX 1205 1821

12 Upsher

13 None

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15 OTHER EXHIBITS REFERENCED PAGE

16 Commission

17 CX 366 1837

18 CX 544 1904

19 CX 557 1920

20 CX 576 1901

21 CX 887 1836

22 CX 1042 1810

23 CX 1092 1828

24 CX 1103 1845

25 CX 1576 1916

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1	Commission	
2	CX 1610	1828
3	Schering	
4	SPX 5	1915
5	SPX 9	1823
6	SPX 12	1848
7	SPX 58	1839
8	SPX 130	1831
9	SPX 131	1832
10	SPX 217	1846
11	SPX 241	1826
12	SPX 243	1838
13	SPX 244	1840
14	SPX 245	1841
15	SPX 255	1844
16	SPX 257	1847
17	SPX 264	1835
18	SPX 267	1780
19	SPX 872	1892
20	SPX 1208	1817
21	SPX 1209	1807
22	SPX 2062	1852
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24	Upsher	
25	None	

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1 FEDERAL TRADE COMMISSION

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3 In the Matter of:)

4 SCHERING-PLOUGH CORPORATION,)

5 a corporation,)

6 and)

7 UPSHER-SMITH LABORATORIES,) File No. D09297

8 a corporation,)

9 and)

10 AMERICAN HOME PRODUCTS,)

11 a corporation.)

12 -----)

13

14 Tuesday, February 5, 2002

15 9:30 a.m.

16 TRIAL VOLUME 9

17 PART 1

18 PUBLIC RECORD

19 BEFORE THE HONORABLE D. MICHAEL CHAPPELL

20 Administrative Law Judge

21 Federal Trade Commission

22 600 Pennsylvania Avenue, N.W.

23 Washington, D.C.

24

25 Reported by: Susanne Bergling, RMR

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1 P R O C E E D I N G S

2 - - - - -

3 JUDGE CHAPPELL: Good morning, everyone.

4 ALL COUNSEL: Good morning, Your Honor.

5 JUDGE CHAPPELL: Let's reconvene docket 9297.

6 Mr. Levy, I remind you you're still under oath.

7 THE WITNESS: Yes, sir.

8 JUDGE CHAPPELL: Where were we? Any cross exam
9 by the respondents of this witness?

10 MS. SHORES: Yes, Your Honor.

11 JUDGE CHAPPELL: You may proceed.

12 Whereupon--

13 NELSON L. LEVY

14 a witness, called for examination, having previously
15 been duly sworn, was examined and testified further as
16 follows:

17 CROSS EXAMINATION

18 BY MS. SHORES:

19 Q. Good morning, Dr. Levy.

20 A. Good morning, Ms. Shores.

21 Q. My name is Laura Shores, we met once before, if
22 you recall.

23 A. Yes.

24 Q. I'd like to start out by -- I'm going to give
25 you a booklet of exhibits, that's the way we have been

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1 doing it so far in the hearing.

2 With Your Honor's permission, I'd like to
3 approach the witness. Permission to approach?

4 JUDGE CHAPPELL: Yes, you may.

5 BY MS. SHORES:

6 Q. I'm going to start out by asking you some
7 questions about niacin generally, okay?

8 A. Okay.

9 Q. Niacin is a vitamin, correct?

10 A. Yes.

11 Q. And it's been around for a long time, right?

12 A. Yes.

13 Q. And you agree that niacin will reduce a
14 patient's total cholesterol level. Is that correct?

15 A. In high doses. You know, you're asking me
16 about the -- you're first asking me about it as a
17 vitamin, and its use in lowering cholesterol is at
18 much, much higher doses than when it's used as a
19 vitamin.

20 Q. All right, but at high doses, it reduces a
21 person's total cholesterol level, correct?

22 A. Yes, it does.

23 Q. And it will lose LDL cholesterol. Is that
24 right?

25 A. Yes.

1 Q. And that's the bad kind of cholesterol?

2 A. Some LDL is now thought to be -- well, yes.

3 Q. So, reducing LDL is good.

4 A. From what I now understand, Ms. Shores,
5 reducing all LDL may not be good, because there is
6 apparently some good and some bad components of LDL,
7 but I don't want to nit-pick. Generally, yes, it's
8 good to reduce LDL.

9 Q. Thank you.

10 Niacin also reduces triglycerides. Is that
11 correct?

12 A. That's correct.

13 Q. And what are triglycerides?

14 A. Triglycerides are a form of fat that are also
15 associated but less -- less clearly with cardiovascular
16 disease, also with pancreatitis and some other things.

17 Q. So, triglycerides are a blood lipid?

18 A. Yes.

19 Q. And that's another word for fat, lipid?

20 A. Yes.

21 Q. And reducing triglycerides is generally good,
22 correct?

23 A. Yes.

24 Q. Now, niacin also reduces something called
25 Lp(a). Is that right?

1 A. Yes.

2 Q. And that another kind of lipid that's not good
3 for you?

4 A. As I understand it, it's less clear in terms of
5 what the role of lipoprotein A is in various and sundry
6 disease states. It's one of the -- as I think I
7 testified earlier, there's a -- all this stuff with
8 blood lipids is in a -- is always in a state of flux.

9 Q. So, you don't know whether reducing lipoprotein
10 A, Lp(a), is good?

11 A. Yes, I don't want to -- I don't want to
12 nit-pick with you. As I understand it, there is not as
13 widespread agreement about the value of reducing Lp(a)
14 as there is, say, about the reducing of total
15 cholesterol and the reducing of LDL.

16 Q. It's fair to say, Dr. Levy, that at least some
17 doctors and physicians and scientists think that
18 reducing Lp(a) is good, right?

19 A. Yes.

20 Q. Now, niacin also raises HDL. Is that right?

21 A. Yes.

22 Q. And HDL is generally known as the good kind of
23 cholesterol?

24 A. In general, yes.

25 Q. Okay. So, raising HDL is good, correct?

1 A. With the same caveat as before, the answer is
2 yes.

3 Q. What's the caveat?

4 A. Again, this -- this whole field of lipid
5 biochemistry seems to be, as is all elements of medical
6 research, in a dynamic state, and I think some experts
7 are now saying that there are also bad high-density
8 lipoproteins. You know, the term "high-density" just
9 means, you know, it's got a high density, so there are
10 a multitude of chemicals that can be included under
11 that category, and I think some people now think that
12 some of them may have deleterious effects.

13 Q. Is it not fair to say, Dr. Levy, that most
14 scientists, physicians, think that raising HDL is good?

15 A. Yes.

16 Q. So, niacin reduces the bad kind of blood
17 lipids, generally speaking.

18 A. Yes.

19 Q. And elevates the good kind of blood lipids. Is
20 that correct?

21 A. Yes.

22 Q. And niacin is the only cholesterol drug to move
23 all the lipids in the right direction. Isn't that
24 correct?

25 A. I don't think that that is entirely correct. I

1 think --

2 Q. You don't think that's right?

3 A. The -- the three major I think widely accepted
4 elements of therapy for hyperlipidemic conditions are,
5 as you pointed out, total cholesterol, lowering LDL and
6 raising HDL. The others are less clear. And niacin is
7 not the only one that does that, that does -- that has
8 the therapeutic -- the therapeutically beneficial
9 effect on those three parameters, that is, total
10 cholesterol, LDL level and HDL.

11 Q. Well, all right, Dr. Levy, if you assume with
12 me -- I think you said that some doctors, at least, or
13 some physicians, some scientists say that lowering
14 Lp(a) is good. Isn't that right?

15 A. Yes.

16 Q. Can you name another cholesterol drug that
17 moves the three that you've spoken about as well as
18 Lp(a) in the desired direction?

19 A. No.

20 Q. And niacin's effects on blood lipids have been
21 shown to reduce the incidence of coronary artery
22 disease, correct?

23 A. I believe so, yes.

24 Q. Well, you believe so or you know so?

25 A. I have to say -- as I've said, I'm not -- I've

1 never presented myself as a Joe Goldstein with
2 up-to-date leadership expertise in this area. I
3 believe that that is correct.

4 Q. But you're not sure?

5 A. Whether niacin has been shown conclusively to
6 reduce the incidence of cardiovascular disease and
7 heart attacks?

8 Q. Whether niacin's effects on blood lipids have
9 been shown to reduce the incidence of coronary artery
10 disease.

11 A. Oh, I misunderstood you. Yes, those effects
12 have definitely been shown to reduce -- yes.

13 Q. In fact, niacin has been shown to reduce
14 mortality. Is that correct?

15 A. The -- the changes in blood lipids that you
16 described for niacin, that is, the changes in those
17 three indices, have been shown to reduce the incidence
18 in heart attacks and to reduce the incidence in
19 mortality. Whether niacin itself has been shown to do
20 that I can't say. I just don't know.

21 Q. You don't know?

22 A. I don't know.

23 Q. Well, in any event, niacin clearly has some
24 benefits as a drug for the treatment of high
25 cholesterol, correct?

1 A. Yes.

2 Q. And these benefits were recognized by the
3 pharmaceutical industry in the mid-1990s, right?

4 A. Earlier than that.

5 Q. Okay, but it was recognized in the mid-1990s,
6 too, right?

7 A. Yes.

8 Q. Schering, Kos and Upsher-Smith weren't the only
9 ones to recognize that, were they?

10 A. That's correct, yes.

11 Q. Now, the benefits of niacin were also then
12 known to doctors, weren't they?

13 A. Some, yes.

14 Q. How about cardiologists?

15 A. Yes.

16 Q. What is the worldwide cholesterol market for
17 drugs today -- I'm sorry, the worldwide market for
18 cholesterol drugs today?

19 A. For drugs that lower -- that --

20 Q. Cholesterol.

21 A. -- that lower total cholesterol, just all of
22 them?

23 Q. Yes, all of them.

24 A. Today, in the year 2002, I don't think I've
25 seen a 2002 or even a 2001 number, but it's probably

1 \$13-\$14 billion.

2 Q. And what was it in 1997?

3 A. Then, it was about I think -- about \$6 billion,
4 \$7 billion.

5 Q. Are you sure it's not closer to \$8 billion?

6 A. I'm sorry?

7 Q. Are you sure it's not closer to \$8 billion?

8 A. That may be the case.

9 Q. Could be?

10 A. Yes.

11 Q. Now, it's a growing market, correct?

12 A. Yes, it is.

13 Q. And it sounds like it's grown quite a bit since
14 1997. Is that right?

15 A. Yes, it has.

16 Q. So, a niacin drug, assuming it could get over
17 the problems with side effects that you discussed in
18 your direct examination, could make a lot of money,
19 even if it got a tiny bit of the cholesterol market.
20 Isn't that fair to say?

21 A. I guess it depends on what you define as a
22 "tiny bit."

23 Q. How about 1 percent?

24 A. One percent of \$13 billion is a lot of money.

25 Q. And 1 percent of -- let's assume it was \$8

1 billion or so in 1997, 1 percent of that is a fair
2 amount of money, isn't it?

3 A. Yes.

4 Q. Now, back in the mid-1990s, it was the hope of
5 people in the pharmaceutical industry that a way of
6 presenting niacin without the side effects could be
7 found, correct?

8 A. Did you say "hope"?

9 Q. I said "hope."

10 A. Yes.

11 Q. And the side effects that you identified are
12 flushing, right? That's one.

13 A. Yes.

14 Q. And the other is liver toxicity. Is that
15 correct?

16 A. That is -- that is another, yes.

17 Q. Well, those are the two main ones?

18 A. Well, there are more elements than just the
19 flushing. There is the itch, the redness. I think the
20 constellation of those -- of those three things are
21 what led to the very, very poor patient compliance with
22 that drug, as well as -- as you well know, there were
23 some dermatologic side effects also associated with
24 niacin.

25 Q. Well, but those are all associated with the

1 flushing reaction. That's all a product of the same
2 reaction to the drug. Is that right?

3 A. There were some other side effects, but the
4 major ones you have -- are -- you know, you have stated
5 correctly, the flushing, the itching, the redness and
6 the hepatotoxicity.

7 Q. Okay. And hepatotoxicity, since I can't quite
8 say that, I'll just refer to as liver toxicity, if
9 that's all right with you.

10 A. Yes.

11 Q. All right. Now, flushing is not really a
12 health problem, right?

13 A. I don't want to find myself, you know,
14 nit-picking words with you. I would say yes, it is a
15 health problem, and it's something that bothers
16 patients, that -- particularly one that's iatrogenic,
17 that's caused by something that we do, is a health
18 problem.

19 Q. I'm sorry, particularly when it's what?

20 A. I used the term "iatrogenic," that means
21 doctors caused it, and so I would not say that the
22 flushing caused by niacin is not a health problem.

23 Q. Well, does it -- is it going to make a person
24 sick?

25 A. Yes, he's got -- you know, it's like a cold. A

1 cold is a health problem. It makes us feel bad. It
2 doesn't necessarily take our lives.

3 Q. Okay. Is it a safety issue?

4 A. To be honest, I don't know, because it has a
5 vascular component to it, and if one has an
6 inappropriate dilatation, for instance, of blood
7 vessels on the skin to cause flushing, I have no idea
8 what's happening internally. So, I don't think that
9 one, you know, can say whether it's a health issue or
10 isn't a health issue, whether it has more deleterious
11 effects or doesn't. It -- I certainly don't know.

12 In the immunologic world, which I do know a
13 little bit better, if you have an inflammatory reaction
14 on the skin, it usually means that there's also an
15 inflammatory reaction going on underneath the skin, and
16 so the fact that you only see it on the skin doesn't
17 mean that it's -- that something deleterious is not
18 happening internally. So, I can't speculate about
19 that. I don't know the answer to that question.

20 Q. Fair enough.

21 Now, in your direct testimony, Dr. Levy, you
22 focused on mainly what you call was Schering's lack of
23 due diligence. Isn't that correct?

24 A. Would you repeat that, please?

25 MS. SHORES: Do you want to read it back?

1 (The record was read as follows:)

2 "QUESTION: Now, in your direct testimony, Dr.
3 Levy, you focused on mainly what you call was
4 Schering's lack of due diligence. Isn't that correct?"

5 THE WITNESS: I don't think that's what I
6 focused mainly upon. I focused upon a number of
7 issues, and that was one of them.

8 BY MS. SHORES:

9 Q. Well, a substantial portion of your testimony
10 was to compare what Schering did when it was evaluating
11 Niacor with what it had done when evaluating other
12 drugs. Isn't that correct?

13 A. Yes, I spent a time on that, as I did on some
14 of the other elements of my opinion. You used the term
15 "mainly. I'm not arguing with you that I spoke -- you
16 know, that I discussed that at length, but I -- I'd
17 like not to be characterized as that's being the, if
18 you will, the main thrust.

19 Q. Well, as compared with the amount of time you
20 spent talking about the side effects of niacin, you
21 spent a lot more time talking about Schering's lack of
22 due diligence. Isn't that correct?

23 A. Yes.

24 Q. Now, in your report, your expert report, you
25 focus more on what you describe as the major flaws of

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1 Niacor. Isn't that fair to say?

2 A. I haven't counted the number of pages I've
3 spent on each of those issues, but I think some
4 descriptions take more words or more pages than others.
5 It doesn't mean that one is more important than the
6 other. Sometimes one can enunciate a -- you know, a
7 vitally important concept in one line, and that doesn't
8 mean it's less important than one that somebody might
9 have spent, you know, four reams on.

10 So, I don't think you can -- where I'm
11 objecting to you is in your trying to weigh the
12 importance of the various things I said by the number
13 of pages I devoted to them. That I don't think is an
14 accurate thing to do.

15 Q. Okay. You will admit, sir, that the alleged
16 side effects of Niacor were more prominently featured
17 in your expert report than was a comparison of
18 Schering's due diligence efforts with respect to Niacor
19 and other pharmaceuticals. Is that fair to say?

20 A. No, it's not fair to say for the reasons I just
21 said.

22 Q. Your report was 32 pages long. Is that
23 correct?

24 A. I don't know. I can look at it.

25 Q. Do you want to take my word for it or do you

1 want to look at it?

2 A. I'll take your word for it.

3 Q. And can you tell us where the section in your
4 report entitled Other Agreements Where Schering was a
5 Licensee appears?

6 A. Towards the end of the report, but I'm not -- I
7 don't know the page number.

8 Q. Well, why don't we take a look at it.

9 A. Okay. Okay.

10 Q. Go to page 25. I'm going to try to put it on
11 the ELMO, see if this works.

12 A. Okay.

13 Q. Do you see at the bottom of page 25 where it
14 says, "Other Agreements Where Schering Was the
15 Licensee"?

16 A. Yes, I do.

17 Q. And we have got four lines of text on that
18 page, right?

19 A. Yes.

20 Q. Let's go to page 26. We've got three lines of
21 text on that page. Is that right?

22 A. Yes.

23 Q. We've got three pages of a table in your
24 report. Is that correct?

25 A. Yes.

1 Q. And that's a table that compares Schering's
2 in-licensing agreements?

3 A. Yes.

4 Q. And then when you get past that table on page
5 30, you're on to another subject, correct? In fact,
6 you're at your summary comments.

7 A. Yes.

8 Q. So, we don't have a lot of text in your report
9 about comparing Schering's various in-licensing
10 agreements, do we?

11 A. Yes, other than the three tables.

12 Q. Right. And this is all at the end of your
13 report?

14 A. Towards the -- you know, towards the back of
15 the report, yes.

16 Q. All right. And the point you were making in
17 your report, Dr. Levy, was that if Schering had just
18 conducted due diligence at the same level that it had
19 done with respect to these other licensing agreements,
20 it would have found the major flaws that you say
21 existed in Niacor. Isn't that right?

22 A. No, I don't think I'm saying that. I'm saying
23 that they didn't conduct due diligence. You know, what
24 they would have found no one can know, because it
25 wasn't done.

1 Q. Well, all right, in your report you said that
2 Schering either missed or ignored major flaws.

3 A. Yes, and during what I refer to as the
4 preliminary evaluation, there are some things that
5 basically jumped off the page to me in their
6 preliminary -- that preliminary information, that
7 quarter inch thick dossier that I -- you know, I spoke
8 of in my direct testimony, and I think the whole point
9 of a preliminary evaluation is to identify those areas
10 that would require further investigation or among the
11 major points of the preliminary evaluation, and I
12 thought there were some things that, as I said, jumped
13 off the page at me, and I was somewhat surprised that
14 they didn't seem to elicit the sort of assiduousness
15 that I would have expected from companies like
16 Schering-Plough.

17 Q. Okay. And one of the things that jumped off
18 the page was the flushing that was associated with
19 Niacor, right?

20 A. No, I don't -- I'm stuck in my own metaphor of
21 "jumping off the page." I think that the flushing was
22 something that was seen. I don't think it would -- I
23 think it was something that was probably expected, and
24 I don't -- I was not really referring to the flushing
25 as one of the -- the -- you know, the biggies that

1 jumped off the page, if you will.

2 Q. Well, let me try this out on you.

3 A. Okay.

4 Q. One of the things that jumped off the page was
5 liver toxicity, right?

6 A. Yes, or -- no -- again, I -- I don't understand
7 this process as well as I might like to, and I don't
8 really want to, you know, to argue semantics with
9 you --

10 Q. Well, here's the way it works. I ask a
11 question, and you give me an answer, okay?

12 A. And I'm trying to be accurate and trying to be,
13 you know, respectful of that. What was done was
14 screening tests, and they suggested the strong
15 possibility of liver toxicity. That's all there was.
16 And what I said in my report was that that should have
17 been followed up. I didn't say -- I don't think anyone
18 can say that an elevation of a couple of enzymes is
19 evidence of liver toxicity.

20 Q. Well, in your report, you said that it was
21 clear evidence of liver toxicity, did you not?

22 A. I don't recall what I said in my -- in my
23 report about that particular point.

24 Q. Well, we'll take a look at it.

25 A. Okay.

1 Q. Let's go to page 13. I'm looking at a number 2
2 underneath the letter H. Do you see that?

3 A. 2-H, okay.

4 Q. It says, "The drug showed clear evidence of
5 hepatotoxicity that, unless mitigated, would be
6 unacceptable."

7 A. Yes.

8 Q. That's what it says in your report, right?

9 A. That's right, and I think the key point there
10 is "unless mitigated."

11 Q. Dr. Levy, if you could just answer the question
12 yes or no if it calls for a yes or no answer.

13 A. I'm sorry, yes.

14 Q. That's what it says in your report, right,
15 "clear evidence of hepatotoxicity," right?

16 A. Yes.

17 Q. And again, hepatotoxicity means damage to the
18 liver, correct?

19 A. Yes.

20 Q. Now, it's your position that the data that
21 Upsher provided to Schering, just that data, showed
22 that Niacor had clear evidence of liver damage that
23 would make the drug unacceptable, right?

24 A. I can't say yes to that question for the
25 reasons I just said.

1 Q. All right. So, it showed clear evidence of
2 hepatotoxicity that unless mitigated would be
3 unacceptable, right?

4 A. Yes.

5 Q. Now, there's a fair amount of discussion in
6 your report about liver toxicity, isn't there? I said
7 a fair amount.

8 A. I don't know what a "fair amount" is.

9 Q. Well, there's a lot more discussion of it in
10 your report than we heard about during your direct.
11 Isn't that correct?

12 A. That's correct.

13 Q. Dr. Levy, isn't one of the reasons that you've
14 shifted emphasis away from liver toxicity is that you
15 used the wrong standard in judging whether there was
16 liver toxicity associated with Niacor?

17 A. Absolutely 100 percent unadulteratedly not.

18 Q. Okay. Well, the standard that you use is
19 different from the one the FDA uses, is it not?

20 A. Not correct.

21 Q. Well, we'll see.

22 Now, the evidence that you focused on in your
23 report was the data showing the number of patients in
24 Upsher's clinical trials who had liver enzyme
25 elevations at 1.5 times the upper limit of normal,

1 correct?

2 A. The data that I cited in my report?

3 Q. That's correct.

4 A. Yes.

5 Q. Now, there are two liver enzymes that we're
6 talking about here. Is that right?

7 A. Yes.

8 Q. And one is ALT?

9 A. Yes.

10 Q. And the other is AST?

11 A. Correct.

12 Q. And what is the normal range of ALT?

13 A. That varies from -- from laboratory to
14 laboratory. In general, the upper limit of normal is
15 in the twenties.

16 Q. And what about AST?

17 A. I think it's about the same.

18 Q. So, assuming that --

19 A. Now, remember, that is the upper limit of
20 normal, upper limit of normal --

21 Q. Right, that is the upper limit of normal.

22 A. Right.

23 Q. So, if somebody had 1.5 times the upper limit
24 of normal and the upper limit of normal was 20, that
25 would mean that somebody had an enzyme elevation of 30.

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1 Is that correct?

2 A. No, one and a half times 25 would be more than
3 30.

4 Q. I'm sorry, I thought you said that 20 was the
5 upper limit of normal.

6 A. In the twenties. Twenty-five is more or less
7 where --

8 Q. Okay. And what's 1.5 times 25?

9 A. It's in the thirties.

10 Q. Now, you used in your report -- you had a table
11 showing the number of patients from Upsher's trials
12 that had elevated enzymes at 1.5 times the upper limit
13 of normal, right?

14 A. Yes.

15 Q. And that information was taken from the data
16 package that Upsher had provided to Schering, correct?

17 A. Yes.

18 Q. And the numbers taken from that data package
19 most likely represent a single test on those patients,
20 correct?

21 A. I don't know. That's one of the questions.

22 Q. Well, did you know that when your deposition
23 was taken?

24 A. No.

25 Q. Referring to page 18 of your deposition, let me

1 see if I can get this going. Can you see sort of in
2 this range here --

3 A. Oh, I was looking for the highlighted portion
4 above it --

5 Q. Yes, I didn't highlight this part.

6 Do you see this where it says --

7 MR. SILBER: Your Honor, if they are going to
8 focus in on a very small portion of Dr. Levy's
9 testimony from his deposition, I think it would be fair
10 for him to have a full copy of this so he could see it
11 for context.

12 MS. SHORES: I'm happy to read the whole answer
13 if that will help.

14 JUDGE CHAPPELL: Do you have a copy of his
15 transcript?

16 MS. SHORES: We do.

17 JUDGE CHAPPELL: Objection sustained.

18 MS. SHORES: Permission to approach, Your
19 Honor?

20 JUDGE CHAPPELL: You may.

21 THE WITNESS: What page is that on?

22 BY MS. SHORES:

23 Q. Page 18.

24 A. Okay.

25 Q. And I'm referring to the portion of your answer

1 that begins with the word "Unfortunately."

2 A. Okay.

3 Q. And in that paragraph you said, "It most likely
4 represents a single test on those patients."

5 Do you see that?

6 A. Yes.

7 Q. That's what you said at your deposition, right?

8 A. Again, I think that the test that -- the
9 sentence above it is quite germane to the answer, so
10 you're asking me to say yes or no. Yes, that sentence
11 says that it most likely represents a single test. The
12 sentence above that I think is the significant context
13 of that, so...

14 Q. Dr. Levy, the question was whether at your
15 deposition you said, "It most likely represents a
16 single test on those patients."

17 Did you say that or not?

18 A. Yes, I did.

19 MS. SHORES: Your Honor, I'm told that I -- I
20 think I tripped over the microphone wire.

21 JUDGE CHAPPELL: Which microphone?

22 MS. SHORES: It must be mine. If everybody can
23 hear me, I'll continue.

24 JUDGE CHAPPELL: Go ahead. Go ahead and
25 continue.

1 MS. SHORES: All right.

2 JUDGE CHAPPELL: Court Reporter, can you hear
3 her okay?

4 THE REPORTER: Yes, I can. Thank you.

5 BY MS. SHORES:

6 Q. Dr. Levy, are you aware that the FDA told
7 Upsher-Smith that it didn't even need to keep track of
8 liver enzyme elevations at less than two times the
9 upper limit of normal?

10 A. No.

11 Q. You're not aware of that?

12 A. Not aware of that.

13 Q. I believe if you get your booklet there, there
14 should be in it something marked SPX 267.

15 A. Okay, I'm there.

16 Q. Do you see that?

17 A. Yes, I do.

18 Q. And this is a telephone communication record
19 between somebody at Upsher-Smith and somebody at the
20 FDA, correct?

21 A. It seems so, yes.

22 Q. If you will turn to the second page of that
23 exhibit?

24 A. Okay.

25 Q. It says there -- and this is recording, again,

1 a telephone communication between Upsher-Smith and the
2 FDA -- it says that, "He stated that the FDA considers
3 LFTs --" what is LFTs?

4 A. Liver function tests.

5 Q. "-- greater than or equal to three times the
6 upper limit of normal on two occasions to be of
7 clinical significance."

8 Do you see that?

9 A. Yes, I do.

10 Q. It then goes on to say, "With this in mind, he
11 stated that breaking the data into two groups (greater
12 than and equal to two times and greater than or equal
13 to three times) would be sufficient."

14 Do you see that?

15 A. Yes.

16 Q. Have you seen this document before?

17 A. No, I have not.

18 Q. So, this was not among the 10,000 documents you
19 reviewed in preparing your opinion?

20 A. That's correct.

21 Q. Now, in your opinion, Dr. Levy, the Kos
22 product, Niaspan, is superior to Niacor. Is that
23 correct?

24 We're done with that exhibit.

25 A. Oh, I'm sorry.

1 The reason I'm hesitating is the answer that I
2 would give is from what I know about the Kos product
3 and what I know about the Niacor product, the Kos
4 product appears to be superior, yes.

5 Q. Okay. And you testified the other day, right,
6 that the side effects are one of the truly major
7 differences between Niaspan and Niacor, correct?

8 A. That's correct, yes.

9 Q. In fact, in your view, Dr. Levy, the key thing
10 about Niaspan, the Kos product, was that it did not
11 have the apparent liver toxicity that had been seen
12 with previous sustained release niacins, correct?

13 A. One of the key things, yes.

14 Q. Well, you said the key thing, did you not?

15 A. I don't know what I said. I'm trying to answer
16 you honestly now. I mean, it is certainly a key thing.
17 I don't want to be characterized as saying "the key
18 thing." It is a very major difference.

19 Q. Well, I can show you what you said the other
20 day, but -- but --

21 A. I'm trying to answer you honestly now. What
22 I -- whether I used one article the other day and
23 another -- and a different article today, I can't say.
24 I'm trying to answer you honestly today.

25 Q. So, sitting here today, you don't think it's

1 "the" key thing; you think it's "a" key thing?

2 A. In my opinion, it is the most important
3 difference. It is not the only difference.

4 Q. I don't think I implied that it was the only
5 difference, thank you.

6 Now, Dr. Levy, how many patients in Kos'
7 clinical trials for Niaspan had elevated liver enzymes
8 at the level of 1.5 times the upper limit of normal?

9 A. I'm -- I'm not sure I've seen those data. I've
10 seen it at two times. I don't think I've seen it at
11 one and a half times.

12 Q. So, you can't make a direct comparison between
13 the number of patients in Upsher's clinical trials who
14 had elevated enzymes at 1.5 times the upper limit of
15 normal with the number of patients in Kos' clinical
16 trials?

17 A. That's correct.

18 Q. Now, you talked a little bit about the statins
19 on direct examination, did you not?

20 A. Yes, I did.

21 Q. And that's the most popular category of
22 cholesterol-reducing drugs?

23 A. Yes, it is.

24 Q. And from your perspective, the statins are
25 almost perfect drugs. Is that right?

1 A. Perfect in their mechanism of action, yes.

2 Q. Okay. You said they were almost perfect on
3 direct, so I assume that you believe that in some
4 respect, right?

5 A. Yes, yes.

6 Q. Now, how about for the statins, do you know how
7 many patients in their clinical trials had elevated
8 liver enzymes at 1.5 times the upper limit of normal?

9 A. I know the data from the first statin, the --
10 which was probably the least -- it's among the least
11 used now, and that was Mevacor, and there the incidence
12 was less than 1 percent.

13 Q. At 1.5 times the upper limit of normal?

14 A. Oh, I'm sorry, I misunderstood you. I don't
15 believe I know the data on 1.5.

16 Q. Okay. So, do you know the data on 1.5 for any
17 of the statins?

18 A. No.

19 Q. So, you can't compare the number of patients in
20 any of the trials for the statins who had 1.5 times the
21 upper limit of normal with the numbers in
22 Upsher-Smith's clinical trials, correct?

23 A. That's correct.

24 Q. But in any event, you believe that the data
25 that Upsher provided to Schering showing the number of

1 patients with elevated enzymes at 1.5 times the upper
2 limit of normal would have mandated a detailed
3 examination of the effects of Niacor-SR on the liver.

4 A. Absolutely.

5 Q. And this detailed examination should have been
6 done by anybody considering a license of Niacor,
7 correct?

8 A. Absolutely.

9 Q. And such a detailed examination in your opinion
10 would have included at the least an examination of the
11 liver biopsies of those patients, correct?

12 A. No.

13 Q. Well, that's what you said in your report,
14 isn't it?

15 A. I don't recall saying that in my report, no.

16 Q. Let's get it out again. Go to page 8. Have
17 you got page 8, sir?

18 A. Yes.

19 Q. It says there, and I quote, "Such data would
20 have mandated a detailed examination of the effects of
21 Niacor-SR on the liver prior to any consideration of
22 in-licensing the drug. Such detailed examination, in
23 my opinion, would have included, at the least:

24 "Examination of liver biopsies in patients
25 treated with Niacor-SR."

1 That's what it says, right?

2 A. Yes.

3 Q. That's what you said in your report?

4 A. Yes.

5 Q. But you don't believe that anymore?

6 A. Yes, I do believe that.

7 Q. Oh.

8 A. But that wasn't the only thing I said to do.

9 Q. Well, I just asked you about that a few
10 questions ago, and you said that was -- but anyway, you
11 stand by this opinion?

12 A. Yes, I do stand by this opinion.

13 Q. So, you think somebody who was evaluating an
14 in-license of Niacor would have demanded that Upsher
15 track down the patients from its clinical trials,
16 redose them and do liver biopsies on them, correct?

17 A. That's not what I said.

18 Q. Well, let's take a look at your deposition. If
19 you go to page 38 of your deposition, I think I gave it
20 to you.

21 A. Okay.

22 Q. It starts on 38 and carries over to 39. Now,
23 at your deposition I asked you:

24 "QUESTION: Now, how is it that you would
25 expect someone who was considering an in-license of

1 Niacor-SR to do these liver biopsies?

2 "ANSWER:," going to 39 now, "I would expect to
3 see some additional clinical data generated on patients
4 who were dosed with Niacor-SR and liver biopsies
5 obtained. Ideally, I'd like to go back to those
6 patients that had had the enzyme elevations and examine
7 the course that they had following the study and also
8 seek to dose them again and biopsy them again, biopsy
9 them.

10 "QUESTION: So, again, how would you expect
11 someone who was considering an in-license to accomplish
12 that? Would they demand that of in this case Upsher,
13 that they go and perform these liver biopsies?

14 "ANSWER: Yes, it would be quite reasonable to
15 ask the licensor to do these kind of studies."

16 That's what you said in your deposition, right?

17 A. Yes.

18 Q. So, you think it would have been reasonable for
19 somebody to ask Upsher to go find these patients in its
20 clinical trials, redose them and do liver biopsies on
21 them, correct?

22 A. I think that there are --

23 Q. That's a yes or no question.

24 A. The answer is yes, but I would like to offer an
25 explanation of that.

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1 Q. You can try. Go ahead.

2 A. I think that, as I've testified, the liver
3 function tests that were done were screening tests.
4 They were positive. They should have suggested to look
5 further. There are a multitude of things that they
6 could look at further, one of which was a liver biopsy.
7 Simple repeat of the tests, looking at whether the
8 patients' liver function tests reverted to normal;
9 looking at what happened to the patients, did they get
10 liver disease, did they not; looking at some other
11 blood tests. There are a multitude of things that
12 positive screening tests suggests. That was all we
13 saw, a positive screening test.

14 Now, the liver biopsy is the ultimate test to
15 determine whether there was liver toxicity. If, for
16 instance, these same patients who had had the elevated
17 liver biopsies on repeat -- or elevated liver function
18 tests had reverted to normal, if repeat studies in the
19 same patients had shown that they were elevated one
20 time but not elevated repeatedly, then my concern would
21 have been less, but I don't know that from the data,
22 nor did Schering.

23 But if they had had elevated liver function
24 studies, then I think a liver biopsy was in order, and
25 that's what I'm trying to say -- that's what I tried to

1 say here, and that's what I'm trying to say now. I'm
2 not saying that one jumps from a positive LFT to a
3 liver biopsy. There are a multitude of things that you
4 do in between, and that's what I think you're
5 obfuscating by your questions.

6 Q. I don't think I'm obfuscating anything. I'm
7 merely asking you questions based on what you said
8 before, and what you said before, Dr. Levy, was that in
9 your opinion, the kind of detailed examination that
10 somebody considering an in-license should have done
11 would have included, at the least, a liver biopsy of
12 these patients, right?

13 A. With the caveat that I just gave, yes.

14 Q. Well, I'm not sure where the caveat was in that
15 long answer, but that's what you think somebody
16 considering an in-license should have done, correct?

17 A. Yes.

18 Q. And they should have demanded that Upsher do
19 that, right?

20 A. This is a class of drugs that has known liver
21 toxicity, known liver toxicity, and certainly those
22 liver function studies -- those liver function tests
23 that were done should have elicited a strong sense of
24 concern because of the fact that every single sustained
25 release niacin product prior to Niaspan had shown

1 significant liver toxicity, that seeing elevated LFTs
2 should have increased their suspicion and should have
3 led them to go further to investigate whether or not
4 there was liver damage or whether these were just
5 random elevations of LFTs.

6 Q. And to do so, they should have performed liver
7 biopsies, right?

8 A. That is one of the things they could have done.

9 Q. No, that's what they should have done at the
10 least, correct?

11 A. I am -- I am willing -- the opinion I'd like to
12 state today would -- is what I said a moment ago, that
13 liver biopsies are not the first thing that one does,
14 and so if I said in my report or if I've said in
15 previous testimony "at least," then I probably
16 overstated that situation, and I'm willing to admit
17 that.

18 Q. Overstatement, right?

19 A. I'm sorry?

20 Q. It was an overstatement in your report?

21 A. I can't say yes to that. I tried to say it
22 honestly and fairly, what I just said. You'd like to
23 characterize it in a one-word sound bite, and I won't
24 let you do that.

25 Q. Well, Dr. Levy, that's the word you used in

1 your previous answer, didn't you?

2 A. I used a complete sentence. I didn't say I
3 just made an overstatement.

4 Q. So, you don't think you made an overstatement
5 in your report? That's a new question.

6 A. I think that I've obviously led to a
7 misperception on at least one reader's part, yours, and
8 that's that I feel that that was the first thing that
9 should be done and should be done in all cases. I did
10 not mean to imply that.

11 What I'm meaning to imply, what I meant in my
12 report, was that that is one of the things that should
13 be done to follow up potential liver toxicity. That is
14 the definitive test for liver toxicity, and that's what
15 I meant to imply. If I've left it -- you know, a
16 perception other than that, then -- then it was an
17 unintentional mistake on my part, and I'm willing to
18 admit that.

19 Q. Well, let's take one more look at your report
20 on page 8.

21 A. Okay.

22 Q. You say there, "Such data would have mandated a
23 detailed examination of the effects of Niacor-SR on the
24 liver prior to any consideration of in-licensing the
25 drug," right?

1 A. Yes.

2 Q. And you say, "Such detailed examination, in my
3 opinion, would have included, at the least:

4 "Examination of liver biopsies in patients
5 treated with Niacor-SR."

6 That's what it says, right?

7 A. Yes, it does.

8 JUDGE CHAPPELL: Is there an objection?

9 MR. SILBER: Objection, Your Honor. We have
10 been over this page several times. We have been over
11 this point several times. I think Dr. Levy has tried
12 to give his fullest explanation of this statement as
13 honestly and candidly as he can today, and this
14 repeated questioning is just not necessary.

15 MS. SHORES: Your Honor, he said in his last
16 answer or maybe a couple of answers ago that he had
17 created apparently a misimpression in the mind of one
18 reader, that was me. I'm going to ask him whether it's
19 not a fair reading of his report that it says what it
20 says.

21 JUDGE CHAPPELL: Mr. Silber, I agree we're not
22 plowing new ground, but I'm not sure what the answers
23 are myself, so I'm overruling the objection.

24 MR. SILBER: Thank you, Your Honor.

25 BY MS. SHORES:

1 Q. Now, Dr. Levy, you don't think it's a fair
2 reading of your report that what you were saying was
3 that anybody considering an in-license should have done
4 liver biopsies?

5 A. I think that it is a fair reading of my report
6 to conclude that. It is not what I meant.

7 Q. Thank you.

8 I'm going to show you what's been marked for
9 identification as SPX 2063. It's not in your booklet.
10 I'm going to show it to you. I'm going to show it to
11 complaint counsel first, see if you can identify what
12 it is.

13 Permission to approach, Your Honor?

14 JUDGE CHAPPELL: You may.

15 BY MS. SHORES:

16 Q. Let's see if I don't fall down this time.

17 A. No, please, I know what it is.

18 Q. I'd like you to look at that for as long as you
19 need to, and then I'd like to take it back.

20 A. Please, yes.

21 MR. SILBER: Your Honor, it's not clear to me
22 whether this is in evidence or not.

23 MS. SHORES: It's not in evidence, Your Honor.
24 It's just a demonstrative. It's marked for
25 identification purposes only.

1 JUDGE CHAPPELL: Are you objecting to it?

2 MR. SILBER: That was an objection that I will
3 withdraw.

4 JUDGE CHAPPELL: Thank you.

5 BY MS. SHORES:

6 Q. Now, Dr. Levy, I've shown you SPX 2063. What
7 is it?

8 A. I believe it's -- I don't mean to be flippant,
9 but I'm -- when I practiced medicine, they didn't have
10 them that fancy, so I believe that it's a device for
11 percutaneous biopsy.

12 Q. So, this is a -- what you would use to do a
13 biopsy on somebody's liver?

14 A. One of the -- I've never used a device like
15 that. I'm presuming from the area of the questioning
16 and what that looks like that that's what it is.

17 Q. Okay. So, you'll assume with me that this is a
18 liver biopsy needle?

19 A. Yes.

20 Q. I tried to get an 18-gauge needle, that's what
21 you said you used to use in -- when you were doing
22 this.

23 A. That's a little bigger than that, but --

24 Q. Actually, I think it is an 18-gauge, but --

25 A. Oh, is it?

1 Q. Apparently so.

2 Now, I don't know exactly how these things
3 work, but there's a switch on it that says "safety" and
4 then "fire." When you were doing these, did you have
5 needles that said "safety" and "fire"?

6 A. No.

7 Q. Well, can you just explain how it is that
8 needle biopsies work? How does this work?

9 A. I -- how one uses a device like that, as I say,
10 that's a little bit updated version, I think, but in --
11 when I did them, one anesthetized a small area of skin
12 over the right upper quadrant of the abdomen,
13 anesthetized it with something like Xylocaine, and then
14 we had a needle that -- with a -- with what was called
15 a -- it was a trochar, that is, it was a hollow needle
16 with a device that had a point on it that filled the
17 bore of the needle.

18 Then you inserted that into the liver, and then
19 you used suction to remove a small amount of the liver
20 that you, you know, that you passed through, and you
21 pulled it -- you drew it into the needle, and then you
22 withdrew the needle, and you had a piece of tissue, a
23 little core of tissue, and that was in turn mounted on
24 a slide and looked at appropriately.

25 That looks like a lot -- that looks like a

1 better device, because it seems that there are multiple
2 holes in the side, so you will get multiple samples, I
3 presume, from different sites.

4 Q. Okay. And again, I know the ones that you're
5 familiar with didn't have this fire and safety
6 mechanism on it.

7 A. Correct.

8 Q. But is it fair to assume -- you can tell me if
9 it's not -- that there's something that propels
10 whatever it is that goes into your liver and pulls out
11 a chunk of it back through this blue --

12 A. I honestly do not know how those devices work.
13 I have not used them. I don't know.

14 Q. You don't know, all right. Well, for the
15 record, this is a -- what, a seven-inch long needle.
16 Is that about right?

17 A. Yes.

18 Q. And as I understand it, this thing goes through
19 your skin and into your liver, right?

20 A. Yes.

21 Q. And pulls out a little chunk of your liver.

22 A. Yes.

23 Q. Now, the clinical trial from which the table in
24 your report showing the number of patients with 1.5
25 times the upper limit of normal elevation of liver

1 enzymes, that trial was completed in October 1995,
2 correct?

3 A. I don't know when the trial was completed.
4 You're saying that the Phase III pivotal trial that was
5 the subject of that -- I think it was 115, the trial
6 number was 115, I believe, is that what you're
7 referring to?

8 Q. Yes, was over in 1995?

9 A. I don't recall when that trial was completed.

10 Q. Well, is it fair to assume that it was over for
11 some length of time before Upsher-Smith presented the
12 results of it to Schering?

13 A. Yes, yes.

14 Q. And Schering was evaluating the Niacor
15 opportunity in June of 1997, right?

16 A. Yes.

17 Q. So, the clinical trials were over as of that
18 time, right?

19 A. That clinical trial was over as far as I
20 understand it, yes.

21 Q. Patients were going on about their way, right?

22 A. Yes.

23 Q. Now, sir, do you think that the patients from
24 those clinical trials would have -- agree to Schering's
25 request that those patients come back in and get their

1 livers biopsied?

2 A. That is done with patient volunteers. It's
3 part of some clinical research. Would they all have
4 come back to get their livers biopsied by Schering just
5 for the heck of it? I doubt it, but there's
6 compensation offered to patients. I mean, we do
7 clinical trials, and that's certainly not an un -- an
8 impossible circumstance.

9 Q. But you doubt that most of them would have
10 agreed to come back in, get redosed with Niacor and
11 have their livers biopsied. You doubt that, right?

12 A. Yes.

13 Q. But again, you think that anybody considering
14 an in-license of Niacor should have demanded that that
15 be done, right?

16 A. Again, I have to say no. I realize what my
17 report said and what -- the impression that report has
18 left. I've tried to mitigate that as best I can. I
19 think that in my report I was -- I left the impression
20 -- my fault, not the reader's fault -- that that was
21 something that should be done, if you will, earlier
22 than I thought appropriate, that I now -- that I
23 recognize that I wrote that section in a way that is
24 eliciting this line of questioning, and I am not -- I
25 don't have to stand by that -- that demand quite the

1 way you're phrasing it.

2 Q. You left that impression in your deposition,
3 too, didn't you?

4 A. I don't think so, no.

5 Q. Well, we'll look at it again. It's the same --
6 the same place where I pointed you to before. Let's go
7 to page 39. There I'm asking you:

8 "QUESTION: So, again, how would you expect
9 someone who was considering an in-license to accomplish
10 that? Would they demand of in this case Upsher, that
11 they go and perform these liver biopsies?

12 "ANSWER: Yes, it would be quite reasonable to
13 ask the licensor to do these kind of studies."

14 That's what you said then, right?

15 A. Yes.

16 Q. Now, you also think anybody considering an
17 in-license of Niacor would have conducted a detailed
18 examination of the histopathology results from animal
19 toxicology studies done prior to the clinical trials
20 for Niacor, correct?

21 A. Yes. Yes.

22 Q. Is that a yes?

23 And histopathology refers to abnormalities seen
24 during microscopic examination of tissues and organs.
25 Is that right?

1 A. Yes.

2 Q. So, what you're saying is that anybody
3 considering an in-license of Niacor should have looked
4 at the results of these animal toxicology studies
5 before entering into the license agreement, right?

6 A. Yes.

7 Q. Do you know whether animal studies were done
8 with Niacor prior to the clinical trials?

9 A. I've never seen the results of those. I would
10 be surprised if they were not.

11 Q. So, you think that the FDA would have required
12 Upsher-Smith to do animal toxicology studies for a
13 sustained release niacin product?

14 A. I don't know what -- I have no idea what they
15 did before. It's -- it's -- it's typical for someone
16 who's contemplating doing clinical trials on a new drug
17 to do animal studies prior to that. This is an unusual
18 situation in that this -- this drug, niacin, had been
19 around for a long time, and it's possible that it was
20 not required to do animal studies. I just don't know,
21 but I certainly saw nothing.

22 Q. I take it if they had not been required, you
23 wouldn't expect anybody considering a license of Niacor
24 to go look at them, would you?

25 A. No, I don't think that. You know, sometimes a

1 good company in my opinion doesn't just depend upon
2 what the FDA requires. A good company such as
3 Schering-Plough would typically take ownership for this
4 situation and want to know that the compound is safe.
5 This is not a question -- this is not just a regulatory
6 question. This is an ethical question.

7 Q. So, are you saying that Schering, before
8 considering an in-license, should have done its own
9 animal trials with Niacor?

10 A. I didn't say that.

11 Q. Well, then, I guess I don't understand what
12 your reference to Schering is. I mean, you just said
13 that Schering should have taken ownership, correct?

14 A. Yes, that is what I said, and what I -- what
15 I've said in terms of the animal tox studies, I said
16 that they should have looked at them. Now, if the
17 animal tox studies didn't exist, they couldn't look at
18 them. That would be something that Schering would have
19 to then decide, and then Schering's decision-making
20 would say, well, we have patients with high -- you
21 know, a high incidence of elevated LFTs, we can't find
22 any other information, they didn't do tox studies, so
23 Schering would have to then make the decision. Do we
24 wing it and hope this thing is safe or do we look for
25 other data? And among the other data they could have

1 looked at would be animal tox studies.

2 I mean, you're asking me hypotheticals, and I'm
3 trying to answer your questions. All I said in my
4 report was that with those elevated screening tests,
5 they would have tried to find every speck of additional
6 information to give them some comfort or lack thereof
7 about the safety of this drug. They didn't do it.
8 That's what I said, and that's what I'm trying to say
9 today.

10 Q. Are you done with your answer?

11 A. Yes.

12 Q. So, it's fair to say that if animal studies had
13 not been done with Niacor, you wouldn't expect Schering
14 to have gone and looked at them, right?

15 A. No, that's not right. They have the option of
16 performing them themselves. If they -- this is a
17 decision that people looking at the whole constellation
18 of this -- of what this product offers would have to --
19 would have to decide. That's why you involve SPRI.
20 That's why you involve the research people within the
21 company, because these are decisions that have to be
22 made.

23 The question of whether this compound was
24 hepatotoxic was of vital importance to whether it could
25 be licensed and whether it could be ultimately sold

1 safely, and that's why you involve SPRI.

2 MS. SHORES: Would you read the last question
3 back, please?

4 (The record was read as follows:)

5 "QUESTION: So, it's fair to say that if animal
6 studies had not been done with Niacor, you wouldn't
7 expect Schering to have gone and looked at them,
8 right?"

9 MS. SHORES: Your Honor, I would ask the Court
10 to admonish the witness to please answer my question
11 and to not go into lengthy, nonresponsive answers.

12 JUDGE CHAPPELL: Dr. Levy, as we've discussed
13 before, you need to try to listen to the question and
14 answer only the question. Now, I understand there are
15 times when you want to explain. If counsel wants to
16 let you explain, that's fine. If not, on redirect,
17 you're going to be given your chance.

18 THE WITNESS: Okay, I'm sorry, sir.

19 BY MS. SHORES:

20 Q. Let's go back and talk a little bit about the
21 statins. Those are the almost perfect drugs, right?
22 Right?

23 A. Yes.

24 Q. Now, on direct examination, you were asked to
25 name -- give a few examples of the statins, and I think

1 you named Zocor. Can you name any others?

2 A. Sure. Yes.

3 Q. Fair enough. Would you please do so, Dr. Levy?

4 A. I'm sorry. Yes, there's -- excuse me,
5 atorvastatin or Lipitor and Zocor are the two major
6 ones. There's Pravachol. There's Mevacor. There's
7 now Questor. There's Lescol.

8 Q. Now, some of the patients in the clinical
9 trials for some of these statins had elevated liver
10 enzymes, did they not?

11 A. The only data that I've seen is Mevacor, so the
12 answer is in part yes. I don't know about the others.

13 Q. Well, we talked about Lipitor in your
14 deposition, didn't we?

15 A. Yes.

16 Q. So, you've seen the data for Lipitor?

17 A. I believe so, but I'm just not clear about
18 that, Ms. Shores, what data on which statins I've seen.

19 Q. So, you don't recall in your deposition saying
20 that Lipitor at 80 milligrams, the patients in the
21 clinical trials had had elevated liver enzymes at three
22 times the upper limit of normal at the rate of 2.3
23 percent? Do you recall --

24 A. I'm sorry, yes, I -- I was misremembering that.
25 I thought that that was Mevacor, but you're correct,

1 that's right, I did -- that is correct.

2 Q. Okay. So, again, just to give a little context
3 here, 2.3 percent of the patients in the clinical
4 trials for Lipitor at 80 milligrams, the highest dose,
5 had elevated liver enzymes at three times the upper
6 limit of normal, right?

7 MR. SILBER: Your Honor, objection. I'm not
8 sure what Ms. Shores is doing here, if she's trying to
9 impeach the witness with a statement from his
10 deposition. If that's what she's trying to do, I think
11 it's only fair for him to be able to see that
12 statement.

13 MS. SHORES: You absolutely can look at your
14 deposition if you want to. It's at page 22. I wasn't
15 trying to impeach you.

16 THE WITNESS: I -- I do recall those data, and
17 I do recall saying that, and I believe that's accurate,
18 what you just said.

19 JUDGE CHAPPELL: So, if the objection is he has
20 the right to see it, she's agreed with you, are you
21 withdrawing the objection?

22 MR. SILBER: Yes.

23 JUDGE CHAPPELL: Thank you.

24 Ms. Shores, is the mike working now?

25 MS. SHORES: No, I don't think so, Your Honor.

1 JUDGE CHAPPELL: Thank you. We had a
2 technician working on it, and he's gone to get more
3 help. So, you may proceed.

4 BY MS. SHORES:

5 Q. All right. Now, some statin formulations, Dr.
6 Levy, have even higher incidences of elevated liver
7 enzymes associated with them, don't they?

8 A. I'm sorry, some statin formulations?

9 Q. Yeah, some statins have data from their
10 clinical trials showing that an even greater number of
11 patients experienced elevated liver enzymes at three
12 times the upper limit of normal, correct?

13 A. Greater than what?

14 Q. Greater than Lipitor that we just talked about.

15 A. Yes, I believe that's correct.

16 Q. Okay. And sir, are you familiar with the
17 Physicians' Desk Reference?

18 A. Yes.

19 Q. I'll just hold it up and show it to you here.
20 It's a big, heavy book.

21 A. Yes.

22 Q. And what is the Physicians' Desk Reference?

23 A. It's a compilation of the package inserts from
24 most or all of the prescription products available in
25 the United States.

1 Q. And this is what doctors refer to when they
2 want to find out something about the efficacy of a
3 particular drug, correct?

4 A. Some doctors refer to it for some things.

5 Q. Well, it's the Physicians' Desk Reference,
6 isn't it?

7 A. I don't know how to answer your question other
8 than what I just said.

9 Q. Do some doctors have it in their office?

10 A. Yes.

11 Q. And they look up drugs before prescribing them?

12 A. Yes.

13 Q. All right. Now, I'm going to show you what's
14 been marked for identification as SPX 1209. It's in
15 your book, and also I'm going to be showing it on the
16 screen. It's already there.

17 A. I'm sorry, what was the number?

18 Q. 1209.

19 A. Okay.

20 Q. And this is the Physicians' Desk Reference --
21 with your permission I'll call that PDR -- this is the
22 entry for Lescol.

23 A. Yes.

24 Q. Is that right?

25 A. Um-hum.

1 Q. And Lescol is a statin, right?

2 A. Yes, it is.

3 Q. Now, on your screen I've blown up a couple of
4 portions. If you want to use the hard copy, it's at
5 the third page.

6 A. No, this is easier.

7 Q. All right.

8 A. Thank you.

9 Q. And it says there in the portions that I've
10 blown up -- again, this is under Warnings, Liver
11 Enzymes in the PDR --

12 A. Yes.

13 Q. -- it says, "In a pooled analysis of all
14 placebo-controlled studies in which Lescol capsules
15 were used, persistent transaminase elevations (greater
16 than three times the upper limit of normal [ULN] on two
17 consecutive weekly measurements) occurred in 0.2%, 1.5%
18 and 2.7% of patients treated with 20, 40 and 80
19 milligrams."

20 Do you see that?

21 A. Yes, I do.

22 Q. So, according to this, Lescol has a slightly
23 higher number of patients in its clinical trials at one
24 dosage who had elevated enzymes at three times the
25 upper limit of normal, correct?

1 A. Yes.

2 Q. And in the second box that I've blown up there,
3 it says, "In the pooled analysis of the 24-week
4 controlled trials, persistent transaminase elevation
5 occurred in 1.9%, 1.8% and 4.9% of patients treated
6 with Lescol XL (fluvastatin sodium) 80 milligrams,
7 Lescol 40 milligrams and Lescol 40 milligrams twice
8 daily," and then it says, "respectively" under that.

9 Do you see that?

10 A. Yes, I do.

11 Q. So, in this case, at one particular dosage of
12 Lescol, 4.9 percent of the patients had persistent
13 transaminase elevations at three times the upper limit
14 of normal, correct?

15 A. Yes.

16 Q. And just for context, do you recall what the
17 number of patients in Upsher-Smith's clinical trials --
18 do you recall what the number of patients were that had
19 elevated liver enzymes at three times the upper limit
20 of normal was? Do you recall that figure?

21 A. It depends on what dose one looked at. I don't
22 recall.

23 Q. Well, at any dose. What's the highest
24 percentage?

25 A. At three times the upper limit of normal?

1 Q. Yes.

2 A. I didn't focus a great deal on the three times
3 the upper limit of normal. I focused on the one and a
4 half times upper limit of normal.

5 Q. So, you don't know what the rate was at three
6 times the upper limit of normal?

7 A. I know where it was in Mr. Audibert -- in that
8 exhibit, and I certainly could find it, but I don't
9 want to cite a number and then be incorrect.

10 Q. All right, why don't we get it out and show it
11 to you.

12 A. Okay.

13 Q. If you look in your booklet, it's CX 1042.

14 A. Okay.

15 Q. And it's on the page at the bottom marked
16 1600092.

17 A. 92.

18 Q. Okay. And I'd also -- I've also shown this on
19 your screen, it's a little bit clearer there. Do you
20 see that?

21 A. Yes, I do.

22 Q. And looking at the right-hand column, I believe
23 the number is 4 percent. Is that correct?

24 A. Yes.

25 Q. And again, these were two successive elevations

1 at three times the upper limit of normal, right?

2 A. Yes.

3 Q. They weren't persistent elevations, were they?

4 A. There's no evidence -- there's nothing on here
5 that speaks to their -- you know, to their persistence
6 or not.

7 Q. And again, going back to the Lescol entry in
8 the PDR, at one dosage strength, 4.9 percent of the
9 patients had persistent transaminase elevations.

10 A. Persistent during the trial. It doesn't mean
11 persistent forever.

12 Q. Okay. Well, what is the significance of
13 "persistent"?

14 A. Again, I think one of the things I said in my
15 report and one of the things that I would have had an
16 interest in is whether the elevated liver enzyme was
17 transient or whether it persisted while the drug was
18 being given and even whether it persisted after the
19 drug was stopped.

20 Q. And that's important, isn't it, because if --
21 if it's shown that the elevations go down after the
22 drug is stopped, that's less of a problem, isn't it,
23 with the drug?

24 A. It may be less of a problem. It doesn't --
25 it's not necessarily less of a problem.

1 Q. So, what we have here is 4 percent have two
2 consecutive elevations -- this is in Upsher's clinical
3 trials --

4 A. Um-hum.

5 Q. -- two consecutive elevations at three times
6 the upper limit of normal, right?

7 A. Yes.

8 Q. And in Lescol, an approved drug, in one dosage
9 strength, we have 4.9 percent of patients who have
10 persistent elevations, right?

11 A. That's correct.

12 Q. But you don't consider the statins to be toxic
13 to the liver, do you?

14 A. The statins have as a group labeling that liver
15 function studies should be periodically performed and
16 with the idea that -- that the occasional patient may
17 have a problem with it. And so again, I apologize to
18 the Court. I -- you answered -- you wanted a yes or no
19 answer, and I -- there was no yes or no answer for
20 that.

21 Q. That's fine, Dr. Levy. You can explain if you
22 want.

23 And I think you were saying that -- let me see
24 if I get this right -- that with the statins, there's
25 an indication -- in fact, it's in the PDR for all of

1 them -- that the doctor can prescribe them, but they
2 should monitor the patient's liver during the time that
3 they're using the drug, right?

4 A. That's correct.

5 Q. And that's so that if the elevations get too
6 high and they persist, the doctor has the option of
7 taking them off the drug, correct?

8 A. That's correct.

9 Q. It didn't stop those drugs from being approved,
10 did it?

11 A. No.

12 Q. Now, you mentioned another class of drugs the
13 other day used to treat cholesterol called the
14 fibrates. Do you recall that?

15 A. Yes, I do.

16 Q. And I think you said they weren't as widely
17 used as the statins. Is that right?

18 A. Yes, I did.

19 Q. In fact, I think you said their share of the
20 cholesterol-lowering market was going down. Is that
21 right?

22 A. That's correct.

23 Q. And the fibrates have some unpleasant side
24 effects. Is that right?

25 A. Yes.

1 Q. And I think you said they don't work as well as
2 the statins either, right?

3 A. That's correct, at least on the three major
4 indices that we spoke of earlier.

5 Q. Dr. Levy, do you think the FDA would be less
6 likely to approve a niacin or a fibrate with evidence
7 suggesting potential liver toxicity than they would a
8 statin?

9 A. Would you ask that again, please? I'm sorry.

10 Q. Sure. My question is whether you think the FDA
11 would be less likely to approve a niacin or a fibrate
12 that showed some evidence of potential liver toxicity
13 than they would a statin.

14 A. Today? You mean would they approve it today?

15 Q. We can start with today.

16 A. I think the answer is yes. They would be -- if
17 I understand, they would be -- in my opinion, they
18 would be less likely to approve a fibrate or a niacin
19 compound with evidence of hepatotoxicity than they
20 would a statin with analogous evidence.

21 Q. And that's because you think that statins are
22 essentially better drugs for treatment of cholesterol,
23 right?

24 A. No. If I may answer that question --

25 Q. Go right ahead.

1 A. -- the -- the FDA's approval process is a
2 risk-benefit analysis, and they are more forgiving, if
3 you will, of toxicities when a drug is viewed to have a
4 major clinical importance than they are a drug that is
5 of lesser clinical importance.

6 Q. So, let's now shift to say the mid-1990s or the
7 relevant time frame here. Do you think the FDA would
8 be, in doing its risk-benefit analysis, less likely to
9 approve a niacin or a fibrate with evidence suggestive
10 of potential liver toxicity than it would of a statin?

11 A. Yes. I would like to have a chance to --
12 briefly just to say -- to qualify that, if I may.

13 Q. Go right ahead.

14 A. The reason I'm saying yes is that the sustained
15 release niacin compounds have been shown not just to
16 have elevated liver function tests, they have actually
17 been shown to cause a fulminant hepatotoxicity. And
18 so, if you had -- I believe what you're asking me, if
19 you had a statin that had elevated LFTs and if you had
20 a sustained release niacin with elevated LFTs, I think
21 the index of suspicion on the part of the Food and Drug
22 Administration would be higher for the sustained
23 release niacin than they would -- because they have
24 less familiarity with that class of drug and they have
25 had more problems with that class of drug than they

1 have had with the statins, and so they would ask for
2 more information, I believe.

3 Q. All right. Well, let's compare a fibrate and a
4 statin in that regard. Do you think they would be less
5 likely to approve a fibrate with evidence suggesting
6 potential liver toxicity than they would a statin?

7 A. They would be less likely to approve a fibrate
8 with that than a statin, I believe.

9 Q. Can you give me the name of any of the
10 fibrates?

11 A. Yes.

12 Q. And could you do so?

13 A. Sure. There's clofibrate, gemfibrozil,
14 fenofibrate, bezafibrate are the only ones I can think
15 of.

16 Q. And does one of those go by the brand name of
17 Tricor?

18 A. I don't know which of those has the brand name
19 Tricor. The two that have been marketed in this
20 country for some time have different brand names than
21 that. The two that -- bezafibrate and fenofibrate were
22 sold overseas principally, and I don't know their brand
23 names.

24 Q. So, you haven't heard of Tricor? It doesn't
25 ring a bell?

1 A. Tricor?

2 Q. Yes.

3 A. I'm sorry, no.

4 Q. I am going to show you what's been marked for
5 identification as SPX 1208. It's in your booklet, but
6 it's also on your screen there, and that's the PDR
7 entry for Tricor. Do you see that?

8 A. Yes, that's fenofibrate.

9 Q. So, you are familiar with this drug?

10 A. With fenofibrate, yes. I just didn't know its
11 brand name.

12 Q. Now, let's take a look at the warnings for
13 Tricor. There it says -- I am going to read you what
14 it says underneath Liver Function. "Fenofibrate at
15 doses equivalent to 134 milligrams to 200 milligrams
16 Tricor per day has been associated with increases in
17 serum transaminases (AST [SGOT] or ALT [SGPT])."

18 Those are the liver enzymes, right, Dr. Levy?

19 A. Yes.

20 Q. "In a pooled analysis of 10 placebo-controlled
21 trials, increases of greater than three times the upper
22 limit of normal occurred in 5.3% of the patients taking
23 fenofibrate."

24 Do you see that?

25 A. Yes.

1 Q. So, that's even higher than what we've seen so
2 far in the statins, correct?

3 A. Yes.

4 Q. Focusing your attention now on the second
5 highlighted portion there, it refers to another study.
6 It says, "In an 8-week dose-ranging study, the
7 incidence of ALT or AST elevations to at least three
8 times the upper limit of normal was 13% in patients
9 receiving dosages equivalent to 134 milligrams to 200
10 milligrams."

11 Do you see that?

12 A. Yes.

13 Q. Now, why don't we look at the dosage strengths
14 of Tricor to put those numbers in context.

15 I'm now showing you what is in the PDR under
16 Dosage and Administration. It indicates here that,
17 "For the treatment of adult patients with primary
18 hypercholesterolemia or mixed hyperlipidemia, the
19 initial dose of Tricor is 200 milligrams per day."

20 Do you see that?

21 A. Yes.

22 Q. So, in this instance, we have a fibrate with a
23 much higher percentage of patients who had shown
24 elevated liver enzymes at three times the upper limit
25 of normal than even the statins, right?

1 A. I can't say liver enzymes in answer -- in
2 answering that question yes, and there's a -- there's a
3 specific reason for that, if I may again be allowed to
4 elaborate on that.

5 The fibrates have been associated with another
6 side effect called rhabdomyolysis or breaking down the
7 muscle. The confusing thing here is that the SGOT and
8 SGPT enzymes that are indeed found in liver and are
9 associated with breakdown of liver cells also are
10 elevated when muscle cells are broken down, and so
11 the -- the elevated SGPT and elevated SGOT could have
12 been due to liver, could have been due to muscle, could
13 have been due to both, and I'm sure the FDA was aware
14 of that.

15 Q. Well, whatever it was, it didn't stop them from
16 approving Tricor, did it?

17 A. That's correct.

18 Q. Now, I'd like to go to another part of the
19 entry in the PDR for Tricor. This goes back to what
20 you were saying before. It says in here that, "Regular
21 periodic monitoring of liver function, including serum
22 ALT (SGPT) should be performed for the duration of
23 therapy with Tricor, and therapy discontinued if enzyme
24 levels persist above three times the normal limit."

25 Do you see that?

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1 A. Yes.

2 Q. So, that's like the statins, the doctor there
3 is admonished to watch the person's liver function,
4 right?

5 A. Yes.

6 Q. And he has the ability to take the person off
7 the drug if the elevations persist, right?

8 A. Yes.

9 Q. And again, that didn't stop the FDA from
10 approving Tricor, did it?

11 A. No.

12 Q. Now, Dr. Levy, you're familiar with IMS data,
13 are you not?

14 A. Yes.

15 Q. In fact, that's the most accepted and most
16 widely used source of pharmaceutical sales data,
17 correct?

18 A. Yes.

19 Q. I'm going to show you what's been marked as SPX
20 1205. It's in your book, but I'll put it on the ELMO.

21 A. 1205, Ms. Shores?

22 Q. 1205.

23 Do you see there there's an entry for Tricor?

24 A. Yes.

25 Q. This is IMS data, right? It says "Copyright

1 IMS" up in the top left?

2 A. Yes. It's a little bit different. I mean,
3 I -- yes, this looks like the format for IMS data.

4 MS. SHORES: Your Honor, I would move the
5 admission of SPX 1205.

6 JUDGE CHAPPELL: Any objection?

7 MR. SILBER: No objection, Your Honor.

8 MR. CURRAN: No objection, Your Honor.

9 JUDGE CHAPPELL: SPX 1205 is admitted.

10 (SPX Exhibit Number 1205 was admitted into
11 evidence.)

12 BY MS. SHORES:

13 Q. By the way, who makes Tricor, Dr. Levy?

14 A. I don't know.

15 Q. Well, do you see a symbol next to the entry for
16 Tricor there?

17 A. Oh, yes. I think I should know that one.
18 That's Abbott Laboratories.

19 Q. Right. That's where you used to work, right?

20 A. Yes.

21 Q. Now, according to this IMS data, Abbott sold
22 more than \$271 million of Tricor in the United States
23 in 2001 up through November, correct?

24 A. Yes.

25 MS. SHORES: Your Honor, this is a good

1 breaking point. I'm happy to continue if you would
2 like me to.

3 JUDGE CHAPPELL: It's after 11:00. Why don't
4 we recess until 11:20.

5 (A brief recess was taken.)

6 JUDGE CHAPPELL: Ms. Shores, you may proceed
7 with your cross exam.

8 MS. SHORES: Thank you, Your Honor.

9 BY MS. SHORES:

10 Q. Dr. Levy, we have another booklet of exhibits
11 for you, with permission to approach the witness, Your
12 Honor.

13 JUDGE CHAPPELL: You may.

14 MS. SHORES: Let's see if I don't break
15 something else this time.

16 THE WITNESS: Thank you.

17 BY MS. SHORES:

18 Q. Now, Dr. Levy, you said during your direct
19 examination that after the licensing transaction was
20 consummated between Schering and Upsher, neither party
21 showed any serious interest in marketing the drug. Is
22 that correct?

23 A. Yes.

24 Q. In fact, I believe there was an exhibit used,
25 I'll put my photocopy of it on the ELMO.

1 A. Yes.

2 Q. And I think you testified there should have
3 been a project team at Schering involving people from
4 R&D, regulatory affairs and marketing. Is that
5 correct?

6 A. Yes.

7 Q. And you also say there should have been
8 meetings between Upsher-Smith and Schering to
9 coordinate development, address problems and share
10 information. Is that correct?

11 A. Yes.

12 Q. Now, in your report, you wrote that there was
13 almost no communication regarding Niacor-SR between
14 Schering and Upsher-Smith after the execution of the
15 agreement, correct?

16 A. Yes.

17 Q. And that was something you said in your report
18 was very unusual for parties with a supposed mutual
19 interest in the development of a pharmaceutical
20 product, correct?

21 A. Yes.

22 Q. I'd like you to turn to SPX 9 in your booklet.

23 A. I have it.

24 Q. Okay. And that's a fax dated July 16th, 1997
25 from Mr. Kapur at Schering to Mr. Troup at

1 Upsher-Smith. Is that right?

2 A. Yes.

3 Q. And this fax was sent about a month after the
4 deal was entered into. Is that correct?

5 A. Yes.

6 Q. And Mr. Kapur was the one who had negotiated
7 with Mr. Troup over the licensed products, right?

8 A. I don't know that. He was involved with it. I
9 don't know if he was the person who actually negotiated
10 the deal.

11 Q. But he had some involvement with the
12 negotiations?

13 A. Yes, yes.

14 Q. Now, if you will turn to the next page of the
15 exhibit, now, the first paragraph refers to a telephone
16 conversation. Is that correct?

17 A. Yes.

18 Q. And it suggests that Mr. Kapur and Mr. Troup
19 had had a telephone conversation, right?

20 A. Yes.

21 Q. And a telephone conversation is a
22 communication, is it not?

23 A. Yes.

24 Q. Now, the letter also says that Mr. Kapur has
25 given Jim Audibert, director of marketing in

1 international, Mark Halvorsen's name as the contact
2 person for regulatory to schedule a visit to discuss
3 the Niacor-SR submission, correct?

4 A. Yes.

5 Q. Now, Mr. Halvorsen was the manager of clinical
6 and regulatory affairs at Upsher-Smith? Do you know?

7 A. I don't know who he was.

8 Q. He's somebody at Upsher-Smith, right?

9 A. I -- I'm not -- I've seen his name, and I
10 don't -- I haven't put him on one side or the other. I
11 don't recall where he -- where he fits in the
12 organization.

13 Q. Did you read his deposition?

14 A. I don't believe I read Mr. Halvorsen's
15 deposition.

16 Q. Do you know whether he was at Upsher-Smith or
17 at Schering or --

18 A. I really don't know. I don't -- I know I've
19 seen his name. I just don't place him.

20 Q. Okay. Well, this letter goes on to indicate
21 that Mr. Kapur will be contacting Mr. Troup within the
22 following week to discuss how to progress these
23 projects. Is that right?

24 A. I think that's a fair characterization, yes.

25 Q. Well, it's what it says, isn't it?

1 A. Yes.

2 Q. All right, we're done with that exhibit.

3 By the way, this letter counts as a
4 communication, does it not?

5 A. Yes.

6 Q. I'm going to put it right here.

7 Now I'd like you to turn to SPX 241.

8 A. Okay.

9 Q. This is a fax from Mr. Audibert to Mr.
10 Halvorsen dated August 14th, 1997, correct?

11 A. Yes.

12 Q. And that's about two months after the licensing
13 agreement was entered into, correct?

14 A. Yes.

15 Q. And the first sentence says, "Mark, as a follow
16 up to our recent discussions, I would like to arrange a
17 meeting at Upsher-Smith for the week of September 15th
18 so that our regulatory and clinical people can meet
19 with you to review the Niacor-SR dossier and discuss
20 filing strategies," right?

21 A. Yes.

22 Q. Now, that suggests that Mr. Audibert and Mr.
23 Halvorsen had been having discussions, does it not?

24 A. Yes.

25 Q. Those are communications, right?

1 A. Yes.

2 Q. And according to this exhibit, Schering was
3 trying to arrange a meeting, correct?

4 A. Yes.

5 Q. And going back to your demonstrative exhibit on
6 post-deal conduct, the meeting, according to what we
7 just saw, would have included Schering's regulatory
8 people, correct?

9 A. Yes, yes.

10 Q. Should we go back to regulatory?

11 A. Yes, yes.

12 Q. And again, let's go back to SPX 241.

13 A. Okay.

14 Q. It indicates that Schering was trying to
15 schedule a meeting so that the head of Schering's
16 European Regulatory Department could attend, correct?

17 A. I don't see that.

18 Q. Well, let's look at the --

19 A. Oh, yes, I'm sorry.

20 Q. -- next to the last sentence.

21 A. That our head -- yes.

22 Q. Right, that suggests that Schering was trying
23 to arrange a meeting so that the head of its European
24 Regulatory Department could attend, correct?

25 A. Yes.

1 Q. And again, according to this document, the
2 meeting would have included Schering's clinical people,
3 right?

4 A. Yes.

5 Q. Just to go back to CX 1610 for a second, that's
6 your demonstrative. Clinical means R&D, does it not?

7 A. Clinical is part of R&D.

8 Q. Okay. Again, let's go back to 241.

9 A. Okay.

10 Q. This letter is written by Mr. Audibert,
11 correct?

12 A. Yes.

13 Q. And Mr. Audibert is part of Schering's Global
14 Marketing Department, correct?

15 A. Yes.

16 Q. Back to 1610, I'll put a check on marketing,
17 okay?

18 Now, let's go to CX 1092, that's probably in
19 the front of your binder, and let's go to the third
20 page of that exhibit.

21 A. Okay.

22 Q. Have you seen this letter before, Dr. Levy?

23 A. Yes.

24 Q. Now, this would appear to be a letter from
25 Margaret Garske, Upsher-Smith's clinical research

1 coordinator, to Mr. Audibert, correct?

2 A. Yes.

3 Q. And according to this letter, she's sending him
4 copies of four Niacor-SR protocols, correct?

5 A. Yes.

6 Q. What is a protocol?

7 A. I think in this context it means it's the --
8 the -- I'm trying to use a word other than protocol --
9 it's the procedures that will be followed in a clinical
10 trial.

11 Q. Okay, and these were the protocols for the
12 clinical trials that Upsher had already completed,
13 right?

14 A. I don't know what -- what she was referring to
15 here. From this letter, I can't tell.

16 Q. Well, Upsher had completed the two pivotal
17 studies by June of 1997, had it not?

18 A. It said it had completed them. I -- you know,
19 I only saw the report or the summary of the report from
20 one of them. The second one Upsher had maintained that
21 they were going to send the summary to Schering and I
22 don't think ever did. So, I don't really know whether
23 that -- that trial was completed and brought to
24 summary.

25 I don't know what she's referring to in regard

1 to the other two protocols. I mean, I can't tell from
2 this letter what protocols she's referring to.

3 Q. Okay. Well, as of June of 1997, put aside the
4 reports, but Upsher had completed the two pivotal
5 clinical trials, had it not?

6 A. Ms. Shores, I'm not trying to be evasive. I
7 don't know whether they completed those trials.

8 Q. Okay.

9 A. I mean, they said they did, but I have no -- I
10 have seen no evidence of their having done that.

11 Q. Well, according to the materials that
12 Upsher-Smith gave Schering when it was evaluating the
13 license, according to that they had completed those
14 trials, right?

15 A. Yes.

16 Q. And they had also completed two follow-on
17 studies, correct?

18 A. No.

19 Q. No?

20 A. No.

21 Q. Let's go back to 1042. I'm going to have to
22 give you another binder, the binder we already used, if
23 you will turn to CX 1042 in that binder. Do you see it
24 there?

25 A. Yes.

1 Q. If you could turn to the page marked SP 16000,
2 I believe it's 79 at the bottom.

3 A. Yes.

4 Q. Just give me a second to put that on the ELMO.

5 Now, there are four studies indicated there,
6 right, Dr. Levy?

7 A. Yes.

8 Q. And those -- is it your testimony you just
9 don't know whether those had been completed or not
10 before June of 1997?

11 A. Yes, yes.

12 Q. Have you ever seen the protocols for those
13 studies?

14 A. No, I have not. I have seen the protocol --
15 the answer is no.

16 Q. I'm sorry, the answer is?

17 A. The answer is no, I have not seen the protocol
18 for each of these four studies.

19 Q. You have not seen it. Complaint counsel didn't
20 show them to you?

21 A. I don't believe I've seen the protocols for
22 each of these four studies.

23 Q. Okay. Well, we'll pull them out, see if you
24 recognize them, if you could turn to SPX 130 in your
25 binder there.

1 A. SPX 130? In this first binder?

2 Q. No, it's in the --

3 A. The second binder?

4 Q. -- the second binder, I'm sorry.

5 A. May I put this up here?

6 JUDGE CHAPPELL: Yes.

7 THE WITNESS: 130?

8 BY MS. SHORES:

9 Q. Have you seen that before?

10 A. I'm trying to find 130. Oh, here it is, okay.

11 Q. Have you got it now?

12 A. This is the protocol for the 221 study, and I
13 don't believe I've ever seen this before.

14 Q. Okay. It says on there it's an exhibit to Mr.
15 Kapur's deposition. Do you see that?

16 A. Yes, I do.

17 Q. You did read Mr. Kapur's deposition?

18 A. Yes, I did.

19 Q. But you don't recall him testifying about that
20 document?

21 A. I just don't recall this document.

22 Q. Okay, let's look at the next one. This is
23 protocol 920944, and I'm sorry, it's exhibit SPX 131.

24 A. Okay.

25 Q. Have you seen that before, Dr. Levy?

1 A. Let me see this one. Yes, I've seen this one
2 before.

3 Q. And are you saying you just don't know whether
4 these were the ones that were sent with that letter
5 that we were looking at earlier?

6 A. That letter just referred to four protocols.
7 It didn't say which ones.

8 Q. Okay.

9 A. So, I have no idea if it did.

10 Q. Well, how many protocols have you seen, do you
11 know?

12 A. I have seen I believe three protocols, then
13 there was one where all that I saw was the -- it looked
14 like the front page and then a page or two which
15 couldn't have been the complete protocol.

16 Q. Okay. And this was -- this SPX 131 is one of
17 the ones that you saw, right?

18 A. Yes.

19 Q. And you may not know this, but I'll ask you
20 anyway, at the bottom, there are some Bates numbers
21 there, SP 16000298.

22 A. Yes.

23 Q. Do you know whether that means it was produced
24 from Schering's files?

25 A. I believe that SP means it was a Schering

1 document, but --

2 Q. Okay. You don't have any doubt that Schering
3 had this at some point, do you?

4 A. I have -- I can't testify to that. I have no
5 idea what Schering has.

6 Q. Well, you did ask for complaint counsel to give
7 you everything that Upsher had given Schering, didn't
8 you?

9 A. Yes, I did.

10 Q. And you did see this.

11 A. Yes, I've seen --

12 Q. Right?

13 A. -- this.

14 Q. But you don't know -- you can't tell us whether
15 it was among the materials that were represented to you
16 that had been provided to Schering from Upsher. Is
17 that what you're saying?

18 A. I'm confused. I --

19 Q. Well --

20 A. You're asking me whether I know that Schering
21 saw this document. I have no way of knowing that. I
22 presume if it has an SP number on it, it came from
23 Schering to the Federal Trade Commission. So, that's
24 all I can know.

25 Q. Okay. And you don't remember reading any

1 depositions about this protocol, any deposition
2 testimony about it. Is that right?

3 A. Any deposition testimony about this protocol?
4 I don't recall this protocol as having been discussed
5 in any of the depositions.

6 Q. Okay, let's go to the next one. This is SPX
7 264.

8 A. Is that in the back or the --

9 Q. It should be in order of exhibit number in that
10 binder.

11 A. Okay. Yes, I see it.

12 Q. Have you seen that before?

13 A. No, I have not. This was -- this was -- I know
14 I have not seen this, because I specifically asked for
15 the protocol for the 221 study, because the two major
16 studies were the 115 and the 221, and I never got this
17 protocol.

18 Q. So, you asked complaint counsel to give it to
19 you, but they never gave it to you. Is that right?

20 A. I don't know whether I asked complaint counsel
21 for this. I remember not -- I probably did ask whether
22 we had that protocol. I just don't recall specifically
23 asking that, but I'm sure I did, because I was looking
24 for it.

25 Q. Okay, but at any rate, you don't remember ever

1 getting it.

2 A. That's correct.

3 Q. Now I'll show you the last one of these, it's
4 actually CX 887, so that's going to be towards the
5 front of your binder.

6 A. Okay.

7 Q. And that says it's protocol number 920115-D.
8 Is that right?

9 A. Yes.

10 Q. Have you seen that before, Dr. Levy?

11 A. I've seen the protocol for the 115 clinical
12 trial, and I don't -- I don't think that I have seen
13 this exact document. It just looks different from what
14 I recall. I know I've seen the protocol for the 115
15 study, which this seems to be, but I -- but this
16 document just -- it just looks different from what I've
17 seen. I don't know why.

18 Q. Okay. And again, going back to I think it was
19 CX 366, but it's this letter, you can probably just see
20 it on the ELMO there -- well, actually, I jumped one.
21 Hang on one second.

22 I'm sorry, it's CX 366. It's a letter from Mr.
23 Audibert to Ms. Garske saying thank you for sending me
24 the protocols --

25 A. CX --

1 Q. -- you just don't know which protocols these
2 were?

3 Actually, this is the wrong exhibit. I
4 apologize. We're getting there.

5 This is CX 1092, it's the third page, and
6 again, this was the letter from Ms. Garske to Mr.
7 Audibert enclosing four protocols.

8 A. Right.

9 Q. And I take it you just don't know what four
10 protocols those were. Is that right?

11 A. Yes.

12 Q. In any event, this letter does indicate that
13 four protocols were sent from Ms. Garske to Mr.
14 Audibert, right?

15 A. Yes.

16 Q. And again, this is on August 15th, 1997,
17 according to this?

18 A. Yes.

19 Q. And that's two months after the license was
20 entered into?

21 A. Yes.

22 Q. If you could turn now to CX 366, that's
23 probably earlier in your binder.

24 A. Yes.

25 Q. This appears to be a letter from Mr. Audibert

1 back to Ms. Garske saying thanks for sending me the
2 protocols. Do you see that?

3 A. Yes.

4 Q. Have you seen that before?

5 A. I think I have seen -- ah, I think I've seen
6 this letter, yes.

7 Q. It's a communication, isn't it?

8 A. Yes.

9 Q. And in this communication, Mr. Audibert is
10 asking for a list of the investigators who participated
11 in two of the studies. Is that right?

12 A. Yes.

13 Q. Now, again, Dr. Levy, going back to your
14 demonstrative exhibit, that's CX 1610, you think that
15 if Schering were serious about developing Niacor-SR, it
16 would have set up a project team consisting of people
17 from R&D, regulatory affairs and marketing, correct?

18 A. Yes.

19 Q. I'd like you to turn to SPX 243.

20 A. Okay.

21 Q. This is a memorandum dated August 21st, 1997
22 from Mr. Audibert to Rick Veltri, right?

23 A. Yes.

24 Q. And do you know who Dr. Veltri is?

25 A. I -- I don't think I know him specifically.

1 Q. So, you don't know that he is part of SPRI?

2 A. I said I don't know -- I mean, I have seen him
3 under SPRI, but I don't recall him specifically, you
4 know, what his role was in the company.

5 Q. All right, but you have seen him under SPRI?

6 A. I have seen his name, yes.

7 Q. I don't know if you've seen these
8 organizational charts of Schering. This is part of,
9 for the record, SPX 58. According to this, at any
10 rate, someone by the name of Veltri is the vice
11 president of clinical research, cardiovascular/medical
12 and safety services. Do you see that?

13 A. Yes.

14 Q. And that appears to be part of Schering-Plough
15 Research Institute, SPRI, correct?

16 A. Yes.

17 Q. And that's Schering's -- that's Schering's R&D
18 department, right?

19 A. Yes.

20 Q. So, if we could go back to 243, which I think
21 you have there.

22 A. Yes.

23 Q. I'm just going to focus on the text here.

24 Mr. Audibert says to Dr. Veltri that he would,
25 "like us to review the clinical documents but at this

1 time, they are still compiling reports and it is
2 unlikely that we will have something to look at before
3 the end of October."

4 The "they" there is referring to Upsher-Smith,
5 right?

6 A. Yes.

7 Q. "In the meantime, attached are the protocols
8 for four studies."

9 Do you see that?

10 A. Yes.

11 Q. So, Mr. Audibert is sending Dr. Veltri at
12 Schering's R&D department the protocols, correct?

13 A. Yes.

14 Q. If you would go to SPX 244, do you have that?

15 A. Yes.

16 Q. This is a memorandum dated August 21st, 1997
17 from Mr. Audibert to Michael Perelman. Do you see
18 that?

19 A. Yes.

20 Q. And it says that we have recently concluded an
21 agreement with Upsher-Smith for some products and we
22 are reviewing these agreements with various
23 departments.

24 Do you see that, sir?

25 A. Yes.

1 Q. And it asks that Mr. Perelman or somebody named
2 Lisa, it asks that they review these documents (let me
3 know who it is) so that I can get the group together in
4 early September to consolidate comments.

5 Do you see that?

6 A. Yes.

7 Q. By the way, do you know who Mr. Perelman is?

8 A. No, I don't.

9 Q. Let me show you part of SPX 58 for the record
10 again, see if I can zoom in on that. According to this
11 organizational chart, somebody by the name of Perelman
12 is the director of international regulatory affairs,
13 CV/CNS anti-infectives.

14 Do you see that?

15 A. Yes.

16 Q. CV/CNS, that's cardiovascular/central nervous
17 system?

18 A. Yes.

19 Q. If you would go to SPX 245, that's a memorandum
20 dated August 21st, 1997 from Mr. Audibert to a Dr. Bill
21 Carlock. Do you see that?

22 A. Yes.

23 Q. And it says, "Bill, we recently concluded a
24 deal with Upsher-Smith and we need to have various
25 departments review the agreements, especially the

1 proposed manufacturing agreement."

2 Do you see that?

3 A. Yes.

4 Q. Do you know who Dr. Carlock is?

5 A. No, I don't.

6 Q. Let me show you another organizational chart.

7 According to this, someone by the name of Carlock is
8 the director, operations analysis and systems support.
9 Is that what it says?

10 A. Yes.

11 Q. And again, according to SPX 245, Mr. Audibert
12 was asking Dr. Carlock to review a proposed
13 manufacturing agreement. Do you see that?

14 A. Yes.

15 Q. Now, Dr. Levy, don't these documents suggest
16 that Mr. Audibert was setting up a project team?

17 A. No.

18 Q. No?

19 A. No.

20 Q. Well, he sent a memo to somebody at R&D, right?

21 A. Yes.

22 Q. Talked about getting together?

23 A. Yes.

24 Q. Sent a memo to somebody at regulatory affairs,
25 right?

1 A. Yes.

2 Q. And Mr. Audibert, he's in the marketing
3 department, right?

4 A. Mr. Audibert was in the -- in the licensing
5 department. His title -- the department in which he
6 lay -- in which he resided was called Global Marketing,
7 but it seemed to be the department that dealt with
8 in-licensing.

9 Q. Sir, you think that the Global Marketing
10 Department is the licensing department?

11 A. The -- the functions that dealt with
12 in-licensing seemed to be all in that general area
13 under Mr. Lauda, and Mr. Audibert was in one of those
14 sub-departments under Mr. Lauda.

15 Q. So, you don't think that Schering's Global
16 Marketing Department had anything to do with marketing?

17 A. Did it have something to do with marketing,
18 yes. Was it the marketing department, I don't think
19 so.

20 Q. You don't think it was the marketing department
21 for drugs to be sold around the globe?

22 A. I don't think it was the marketing department
23 for drugs to be sold around the globe, yes.

24 Q. All right. Well, let's go back to these
25 communications between Schering and Upsher-Smith after

1 the licensing agreement.

2 By the way, Dr. Levy, you're aware during this
3 time period Schering and Upsher were exchanging drafts
4 of a revised licensing agreement, are you not?

5 A. I have to say that I have seen some
6 communication that there were some drafts going back
7 and forth.

8 Q. Right.

9 A. I don't know whether there were drafts or draft
10 or what it was, but there was some discussion about the
11 agreement.

12 Q. Okay. And one of these drafts is included in
13 your binder at SPX 255, is it not?

14 A. Yes.

15 Q. Do you see that?

16 A. Yes. The letter?

17 Q. Yes.

18 A. Yes.

19 Q. And that's a letter dated June 30th, 1997?

20 A. Yes.

21 Q. It's just about two weeks after the deal was
22 signed?

23 A. Yes.

24 Q. And it's a letter from Mr. Thompson, you'll see
25 that on the bottom. Do you see that?

1 A. Yes.

2 Q. It says here he's the senior commercial counsel
3 - licensing at Schering. Is that right?

4 A. Yes.

5 Q. And that's to Mr. Troup at Upsher-Smith,
6 correct?

7 A. Yes.

8 Q. It attaches a proposed amendment agreement to
9 supplement the June 17th, 1997 agreement, correct?

10 A. Yes.

11 Q. Let's turn to CX 1103. That's going to be in
12 the front where the CXs are.

13 A. 1103?

14 Q. Yep. That's a letter dated July 29th, 1997,
15 right?

16 A. Yes.

17 Q. And that's from Mr. Troup of Upsher-Smith to
18 Mr. Kapur at Schering, correct?

19 A. Yes.

20 Q. It says, "Attached please find the
21 modifications we believe need to be made to the
22 Amendment Agreement that we received from you a few
23 weeks ago," right?

24 A. Yes.

25 Q. Then it says, "This includes a Manufacturing

1 Agreement and modifications to the Confidentiality/
2 Secrecy Agreement signed by Schering on June 11, 1997."

3 Do you see that?

4 A. Yes.

5 Q. And this exhibit attaches some marked-up copies
6 of the agreements, right?

7 A. Yes.

8 Q. And you would say this letter is a
9 communication, I take it?

10 A. Yes.

11 Q. Let's go to SPX 217. That's going to be
12 farther back. That's a fax dated October 27th, 1997
13 from Paul Thompson to Paul Kralovec. Is that correct?

14 A. Yes.

15 Q. Do you know who Mr. Kralovec is?

16 A. No, I don't.

17 Q. So, you don't know whether he's at Upsher-Smith
18 or someplace else?

19 A. I don't know who he is.

20 Q. Okay. This says, "Attached is a copy of a
21 revised agreement for the license agreement."

22 I take it you don't know whether this is
23 referring to an Upsher licensing agreement or some
24 other agreement?

25 A. It's from an attorney at Schering-Plough, and

1 it's discussing Upsher-Smith matters.

2 Q. Yeah. I mean, it says, "I have attempted in
3 this version to address all of the issues presented in
4 the mark-up presented by Ian Troup at the end of July,"
5 right?

6 A. Yes.

7 Q. So, it's safe to assume, isn't it, that Mr.
8 Kralovec works at Upsher-Smith?

9 A. Or outside counsel. I mean, I -- I presume
10 he's involved with Upsher-Smith in some way from the
11 way this reads, but I don't know where he works or who
12 he is.

13 Q. All right. Well, I'll just ask you to assume
14 that Mr. Kralovec works at Upsher-Smith and that by
15 this memorandum, Mr. Thompson from Schering was sending
16 to Mr. Kralovec at Upsher-Smith some more amendments to
17 the agreements, all right?

18 A. I have no problem assuming that. I don't know
19 it.

20 Q. Okay, all right. Let's go to SPX 257 in your
21 book there.

22 A. Okay.

23 Q. This is a fax dated January 12th, 1998, all
24 right, so now we're getting on into the year following
25 the Upsher-Smith agreement of June of 1997, right?

1 A. Yes.

2 Q. This is again from Mr. Thompson to Mr.
3 Kralovec. I take it since you don't know who Mr.
4 Kralovec is, you don't know whether this is a
5 communication between Schering and Upsher, but assuming
6 it is, it looks like Schering is sending Upsher a
7 marked-up copy of the proposed manufacturing agreement,
8 right?

9 A. Yes.

10 Q. And again, assuming that Mr. Kralovec is
11 somebody at Upsher, this would look like a
12 communication between Schering and Upsher, right?

13 A. Yes.

14 Q. All right, let's turn to SPX 12.

15 A. Okay.

16 Q. I'd like you to turn to the second page of that
17 document.

18 A. Yes.

19 Q. Now, that's a fax dated October 21st, 1997 from
20 Mr. Kapur to Mr. Troup, right?

21 A. Yes.

22 Q. And it says there, "I understood from Jim
23 Audibert that your clinical data would be ready by
24 mid-October."

25 Do you see that?

1 A. Yes.

2 Q. And it says, "Please advise if the data is now
3 available and if it is feasible to schedule a meeting."

4 Do you see that, sir?

5 A. Yes.

6 Q. Okay. So, doesn't this indicate, sir, that
7 Schering wanted to look at Upsher's clinical data?

8 A. Yes.

9 Q. And Schering was trying to set up a meeting,
10 was it not?

11 A. Yes.

12 Q. Now, if you go to the first page of that
13 exhibit --

14 A. The same exhibit?

15 Q. Yep. It appears to be a fax dated November
16 7th, 1997 from Mr. Kapur to Mr. Audibert. Do you see
17 that?

18 A. Yes.

19 Q. And it says there that apparently Mr. Kapur ran
20 into Mr. Troup at a meeting, does it not?

21 A. Yes.

22 Q. And it indicates that Mr. Kapur and Mr. Troup
23 discussed very briefly his October 22nd fax. It goes
24 on to say, "Mr. Troup agreed that he would send the
25 Niacor-SR Health Registration Dossier to you," that

1 would be Mr. Audibert, "in segments with information in
2 a format to enable you to make an evaluation instead of
3 waiting for the entire Health Registration Dossier to
4 be completed."

5 Do you see that?

6 A. Yes.

7 Q. Do you know what a health registration dossier
8 is?

9 A. Yes.

10 Q. What is that, sir?

11 A. Documentation necessary for regulatory filing.
12 It's a compilation of clinical and safety data.

13 Q. Okay. So, according to this communication, it
14 looks like Schering is asking Upsher-Smith to not wait
15 until the whole application gets completed before
16 sending information, right, or providing information?

17 A. Yes.

18 Q. I mean, this suggests that Schering is still
19 serious about starting on the application for European
20 regulatory approval, doesn't it?

21 A. I don't think you can say it suggests that.

22 Q. You don't? Why do you think that Mr. Kapur
23 would have been advising Mr. Audibert that he has
24 spoken with Mr. Troup and that Mr. Troup had agreed to
25 send the clinical information in segments? Why do you

1 think that he would have told Mr. Audibert that?

2 A. I think they want that information. I think
3 you're asking me to -- to make conclusions based on a
4 couple of lines in a letter that I can't make.

5 Q. It's kind of hard to do, isn't it?

6 A. Yes.

7 Q. But again, it's your opinion that the parties
8 weren't serious about pursuing Niacor-SR, right?

9 A. Yes, it is.

10 Q. Okay. Now, Dr. Levy, all of these are
11 communications between Schering and Upsher-Smith,
12 right?

13 A. Yes.

14 Q. So -- in fact, these aren't even all the
15 communications between Schering and Upsher-Smith after
16 the agreement, are they?

17 A. I -- they certainly include all the ones that I
18 have seen. Whether there are more, I can't say.

19 Q. How thick is this, sir?

20 A. It's not very thick, actually, because it's --
21 it's a bunch of protocols that are themselves the bulk
22 of that document.

23 Q. Of course. Well, you don't dispute that the
24 protocols were provided to Schering, do you?

25 A. No.

1 Q. And I know this has the protocols in it since
2 they were enclosed at least once. How thick is this
3 stack of documents, Dr. Levy?

4 A. Two inches.

5 Q. Now, Dr. Levy, even if you're right that the
6 parties didn't display sufficient enthusiasm about
7 pursuing Niacor-SR, didn't something else happen during
8 this time frame that might explain that?

9 A. No.

10 Q. No? Well, you know that Kos -- Kos' product
11 came on the market, don't you?

12 A. Yes, I do.

13 Q. And when did that happen?

14 A. In I believe it was either July or August. It
15 was approved in July, and I don't know when it was
16 launched. I presume it was launched shortly
17 thereafter.

18 Q. And how did it do?

19 A. That's a -- I'm not sure how to answer that
20 question.

21 Q. Well, let's see if this helps. This is SPX
22 2062. Do you see that?

23 A. Yes, down here? Yes.

24 Q. Have you got it?

25 A. Yes.

1 Q. It might be in your book, too.

2 A. That's all right, I can see it.

3 Q. And I'll just represent to you, Dr. Levy, that
4 this is taken from published reports of Kos' stock
5 price over time.

6 A. Yes.

7 Q. Okay?

8 A. I see that.

9 Q. And if you look at -- if you look at this
10 document, there appears to be a precipitous drop in the
11 stock price at a certain point.

12 A. Yes, I see that.

13 Q. Do you see that?

14 And when does that fall in time, can you tell?

15 A. It looks like mid-1997.

16 Q. Well, actually, not really, Dr. Levy. It looks
17 more like the fourth quarter, doesn't it, right at the
18 beginning of the fourth quarter, maybe end of the
19 third?

20 A. It's not fourth quarter. It looks like it is
21 somewhere in the third quarter.

22 Q. Well, all right, but what you see there is a
23 pattern of the stock price generally going up, right?

24 A. Yes.

25 Q. In the year 1997, right?

1 A. Yes.

2 Q. In fact, at some point it reaches a high of
3 what's indicated there 44. Do you see that?

4 A. Yes.

5 Q. And then there's a steep decline. Do you see
6 that?

7 A. Yes.

8 Q. Now, when did you say that Kos' product came on
9 the market?

10 A. As I said, I wasn't sure, but it -- this slide
11 indicates that it was launched in August of 1997, which
12 was one of the times that I thought it could have been
13 launched.

14 Q. Does that comport with your recollection?

15 A. Yes.

16 Q. And according to this document, the stock falls
17 pretty precipitously after the launch, right?

18 A. Yes.

19 Q. So, it looks like the Kos product got off to a
20 very poor start. Is that fair to say?

21 A. No.

22 Q. No? You don't think so? Can you think of any
23 other reason why Kos' stock might have fallen then?

24 A. Yes.

25 Q. What's that?

1 A. They grossly over-exaggerated their market
2 projections through their investment banker before they
3 did their IPO, and as usual they didn't meet those
4 projections and the stock price fell. It happens all
5 the time. That's their game.

6 Q. In fact, they were predicting -- well, the
7 market had -- in fact, when they did their IPO, what
8 was the market capitalization of Kos, do you know?

9 A. I don't recall.

10 Q. Oh, you don't recall that. And sir, you don't
11 know whether or not Kos' product was a big success, a
12 big bang success when it first came out?

13 A. You're asking me success and then you're
14 showing me a stock price. They're not the same
15 parameters.

16 Q. Well, how many products did Kos have?

17 A. I believe it had some minor products in
18 addition to this one, but this was by far its major
19 product.

20 Q. And so you just think that -- you just don't
21 know what relationship there is between this
22 precipitous decline in the stock price and the entry of
23 Niaspan?

24 A. Oh, I think that it's definitely -- you know,
25 the precipitous drop in the stock price is definitely

1 related to the launch of Niaspan.

2 Q. Okay. Well, it's fair to say, isn't it, sir,
3 that Niaspan didn't -- didn't do as well as had been
4 expected.

5 A. Been expected by whom?

6 Q. Well, we'll take Kos.

7 A. I have no idea what Kos expected. It's -- it
8 is not atypical for a startup company doing an IPO to
9 grossly overstate its potential earnings. That's how
10 they pump up their stock price. And it's not atypical
11 for investment bankers to comport with that behavior.

12 Q. Okay. Is it fair to say, sir, that Niaspan at
13 the beginning didn't do as well as the market had
14 expected it to?

15 A. The stock market?

16 Q. Is that fair to say? Yeah, the investment
17 community.

18 A. Yes.

19 Q. And at least according to this, the steep
20 decline in Kos' stock price occurred during the same
21 period that you think Schering and Upsher should have
22 been having all these meetings. Is that right?

23 A. Yes.

24 Q. Dr. Levy, you do not represent the scientific
25 community that focuses on cholesterol metabolism, do

1 you?

2 A. I'm not sure I understand that question.

3 Q. The question was whether you represent the
4 scientific community that focuses on cholesterol
5 metabolism. Do you understand that?

6 A. Yes, I do. I mean, I'm -- I don't represent
7 the scientific community in anything, and I -- but I'm
8 part of it, and that is part of the scientific
9 community. So, I just don't know how to answer that
10 question.

11 Q. Well, are you an expert in cholesterol
12 metabolism?

13 A. No.

14 Q. In fact, you can't say what's generally
15 accepted in the scientific community regarding the
16 effects of niacin on blood lipids, can you, sir?

17 A. I believe I can. I testified to that earlier.

18 Q. Do you still have your deposition there, sir?

19 A. Yes.

20 Q. Go to page 191. Have you got that?

21 A. Yes.

22 Q. And the question was:

23 "QUESTION: Sir, is it generally accepted in
24 the scientific community that the effects of niacin on
25 blood lipids reduce the incidence of coronary artery

1 disease?

2 "ANSWER: I can't say what's generally
3 accepted."

4 Do you see that?

5 A. Yes.

6 Q. That's what you said at your deposition, right?

7 A. Yes.

8 Q. You were under oath?

9 A. Yes.

10 Q. The court reporter was there?

11 A. Yes.

12 Q. And you can't speak to what the current state
13 of knowledge is in that area, can you, sir?

14 A. I -- I don't know how to answer that, because
15 "current state of knowledge" is not a clear subject to
16 me. Am I an expert, am I as up to date as I think in
17 my deposition I cited, you know, Joe Goldstein, Nobel
18 Laureate? I don't profess to be on a day-to-day basis
19 up to that level of expertise. Do I know what is
20 generally accepted throughout the scientific and
21 medical community at this point in time, yes. Have I
22 represented myself as an expert scientifically in that
23 area, no.

24 Q. Well, but you really can't speak to what the
25 current state of knowledge is in that area, can you,

1 sir?

2 A. I can't answer that yes or no, because I
3 honestly don't know what you mean by "current state of
4 knowledge."

5 Q. Okay, well, let's go back to your deposition at
6 page 191. Have you got it there?

7 A. Okay.

8 Q. I'm going to read the full answer this time.
9 The question, again, was:

10 "QUESTION: Sir, is it generally accepted in
11 the scientific community that the effects of niacin on
12 blood lipids reduce the incidence of coronary artery
13 disease?

14 "ANSWER: I can't say what's generally
15 accepted. As I said, the state of knowledge about
16 blood lipids and coronary vascular disease is in a
17 state of flux. It's been in a state of flux for 20
18 years or more -- more than 20 years. It was -- we
19 were -- it was in a state of flux when I was in medical
20 school and did some early laboratory studies in this
21 area. So, it changes as we learn more, and I really
22 can't speak to what the current state of knowledge is
23 in this area."

24 Do you see that?

25 A. Yes.

1 Q. That's what you testified to in your
2 deposition, correct?

3 A. Yes, it is.

4 Q. You were under oath then?

5 A. Yes.

6 Q. You understood what the current state of
7 knowledge was then, right?

8 A. Yes, at that time I interpreted it to mean my
9 expertise. In fact, if you read simply the next line,
10 you'll see what I said in my deposition.

11 Q. Yeah, what you said in the deposition is that
12 maybe we, that is the respondents here, ought to
13 consult a guy like Joe Goldstein who might be able to
14 give you more up-to-date information about that.

15 A. Yes. I'm simply --

16 Q. Right?

17 A. -- trying to be honest with you and not
18 represent myself as a Joe Goldstein counterpart.

19 Q. Okay. So, Mr. Goldstein, whoever he is, he
20 would be an expert in the effects of niacin on blood
21 lipids, right?

22 A. He would know an up-to-the-minute state of the
23 scientific knowledge in this area.

24 Q. Okay.

25 A. I would know an up-to-the-month state of

1 scientific knowledge in this area or -- you know,
2 that's why I'm saying I don't know how to define
3 "current state of knowledge."

4 Q. Oh, sir, by your use the term "current," you
5 meant up to this minute?

6 A. What I was meaning there, Ms. Shores, was that
7 I am not a world class expert in the specific area of
8 lipid metabolism and drugs that affect it and that
9 these things change and that I am not trying to
10 represent myself as such an expert.

11 Q. Fair enough.

12 Sir, how long has it been since you practiced
13 medicine?

14 A. Practiced medicine?

15 Q. Yeah.

16 A. Twenty years.

17 Q. Were you a cardiologist?

18 A. No.

19 Q. Were you -- did you specialize in cholesterol
20 diseases?

21 A. No.

22 Q. And when is the last time you prescribed a
23 cholesterol-lowering drug?

24 A. Twenty years ago.

25 Q. Now, you know who Mr. Audibert is, right?

1 A. Yes.

2 Q. And he's the person at Schering who evaluated
3 Niacor-SR, right?

4 A. Yes.

5 Q. Is Mr. Audibert knowledgeable about the market
6 for cholesterol-reducing drugs?

7 A. Again, you used the term "knowledgeable." He
8 knows something.

9 Q. Well, did you read his deposition?

10 A. Yes.

11 Q. Did you see where he said he was?

12 A. You asked me what I think, and I said I think
13 he knows something.

14 Q. Do you think he's knowledgeable?

15 A. Knowledgeable --

16 Q. To me there's a difference between knowing
17 something and being knowledgeable, so I'm asking
18 whether you think Mr. Audibert is knowledgeable about
19 the --

20 A. Well, I'm trying to apply to him the same
21 standard I applied to myself a moment ago when you
22 asked me if I am up to date on the current state of
23 knowledge. I think that by that standard, he is not
24 knowledgeable. By what I think is a fair standard were
25 it applied to me or him, he is knowledgeable. I am not

1 going to say in one instance where I have to allude to
2 a guy like Joe Goldstein that I am knowledgeable and
3 then apply a different standard to Mr. Audibert.

4 Q. Well, we were talking about something slightly
5 different, and maybe we're going too fast, but my
6 question about Mr. Audibert was whether he was
7 knowledgeable about the market for cholesterol-reducing
8 drugs.

9 A. And I think he is knowledgeable.

10 Q. Thank you.

11 Dr. Levy, would you say that you are intimately
12 familiar with sustained release technology?

13 A. Yes, with a qualification.

14 Q. You think you're intimately familiar with
15 sustained release technology?

16 A. Yes.

17 Q. Is Mr. Audibert intimately familiar with
18 sustained release technology?

19 A. I have no idea what Mr. Audibert knows about
20 sustained release technology.

21 Q. You don't? Did you read his deposition, sir?

22 A. Yes, I did.

23 Q. Did you see where he said he was?

24 A. You're asking me --

25 Q. I'm asking you whether you saw that in his

1 deposition.

2 A. Yes, I did.

3 Q. Okay. And you don't have any -- any basis
4 sitting here today to say that he was not being
5 truthful, do you?

6 A. It's not an issue of whether he was truthful or
7 not. It's an issue of interpreting a question.

8 Q. Well, you don't have any reason to think that
9 he's not intimately familiar with sustained release
10 technology, do you?

11 A. It depends on how you define "intimately
12 familiar." You could ask me whether I'm familiar with
13 the moon, and we all are. Am I intimately familiar
14 with the moon? I'm not an astronomer. I'm not an
15 expert on the moon. And I think it's analogous here.

16 Q. Okay. Dr. Levy, have you personally worked on
17 transforming old, known compounds into -- let's add
18 this to the question -- old, known compounds with
19 undesirable side effects into new, sustained release
20 formats?

21 A. Yes.

22 Q. How many of those have you done?

23 A. Two jump into my mind, and I think there's
24 probably more.

25 Q. All right. What was the known compound?

1 A. The known compound in one instance was
2 phentolamine, the drug that's well known to
3 Schering-Plough since it's the active ingredient in the
4 drug they licensed from Zonagen, Vasomax. It's an old
5 drug.

6 Q. And you personally worked on transforming that
7 drug into a new sustained release format?

8 A. Personally work in the laboratory?

9 Q. Yeah.

10 A. No.

11 Q. Okay. Did you personally work on --

12 A. Nor did Mr. Audibert, I might add.

13 Q. -- did you personally work on transforming that
14 drug into a new sustained release format in some other
15 capacity?

16 A. Yes.

17 Q. And what was that?

18 A. As a director of the company, as a director of
19 Zonagen. You know, I was -- I was the only scientist
20 on the board of directors, and I had a great deal of
21 interaction with the various and sundry scientific
22 people at -- you know, at Zonagen, even -- so, the
23 answer is yes.

24 Q. So, by virtue of your position on Zonagen's
25 board of directors, it's your testimony that you

1 personally worked on transforming that drug into a new
2 sustained release technology. Is that correct?

3 A. I said I didn't do it in the laboratory, but --
4 but yes.

5 Q. Okay. Sir, it's been over eight years since
6 you served as an executive at a pharmaceutical company,
7 right?

8 A. Yes.

9 Q. And in fact, you've only had two jobs in the
10 pharmaceutical industry, one at Abbott and the other at
11 Fujisawa, right?

12 A. Yes.

13 Q. Okay. And you were at Abbott for a little over
14 three years in the early 1980s. Is that correct?

15 A. Yes.

16 Q. And you were in charge of its research
17 department for some portion of that time, right?

18 A. All of that time, yes.

19 Q. And generally, you've had experience in
20 overseeing and conducting clinical trials, correct?

21 A. Yes.

22 Q. Do you know what Abbott's R&D budget was when
23 you were there?

24 A. I don't know the -- I don't recall the exact
25 number, no.

1 Q. Can you give me a ballpark?

2 A. I think it was about \$400 million, but I'm
3 really -- that's a real ballpark.

4 Q. Well, it's fair to say, Dr. Levy, that clinical
5 trials would be kind of expensive, isn't it?

6 A. Clinical trials are expensive, yes.

7 Q. Can you give us a range -- is there any way to
8 give us a range of how much they cost?

9 A. Now or then?

10 Q. Let's -- whatever you're more comfortable with.
11 Probably then would be better.

12 A. Well, they were much less expensive then.
13 Clinical trials back then, depending on the nature of
14 the drug, depending on the duration of the trial,
15 depending on the phase of the clinical trial, I mean,
16 you're asking me a very -- a very broad-based question.
17 If you would be a little bit more specific, it would be
18 helpful.

19 Q. You can't give us a range generally?

20 A. Sure, I can give the range of clinical trial.
21 It could cost back then as little as \$50,000 and as
22 much as -- probably back then, a \$20 or \$30 million
23 trial would have been a pretty expensive trial.

24 Q. How about in the mid-1990s?

25 A. The mid-1990s -- really the early 1990s is

1 where it really started to take off in costs, and I
2 think one still can do a clinical trial, a very limited
3 clinical trial for \$50,000 or so or even less maybe,
4 depending on the clinical trial, but clinical trials
5 can get up to \$200 or \$300 million.

6 Q. Now, you were at Fujisawa for, what, about a
7 year in the early 1990s? Is that right?

8 A. Yes.

9 Q. And at that time -- you were at Fujisawa North
10 America, right?

11 A. Yes.

12 Q. And at the time, Fujisawa North America had
13 about \$250 million in sales, right?

14 A. Yes.

15 Q. That's \$250 million, right?

16 A. Yes.

17 Q. And so, sir, you were there for about a year in
18 the early 1990s, right?

19 A. Yes.

20 Q. And when you add that year to the three years
21 that you were at Abbott in the early eighties, three
22 and a half years, the total length of time you've spent
23 as an employee of a pharmaceutical company would be
24 about four years and a little bit. Is that right?

25 A. Yes.

1 Q. How long has Mr. Audibert been an employee of a
2 pharmaceutical company?

3 A. I don't recall exactly. I think it was about
4 20 years.

5 Q. Now, you didn't have any sales responsibility
6 at Abbott or Fujisawa for products outside North
7 America, right?

8 A. That was not under my supervision, that's
9 correct.

10 Q. You didn't have any sales responsibility at all
11 at Fujisawa North America -- I'm sorry, at Fujisawa or
12 Abbott for products outside North America, right?

13 A. No, that's not entirely correct.

14 Q. Well, that's because you count among that the
15 fact that you were the president of Fujisawa -- well,
16 what products did Fujisawa North America sell outside
17 of North America?

18 A. The -- the reason that I'm trying to qualify
19 that a little bit is that, as I said to you, as -- as
20 the president of the North American operation, I sat on
21 the worldwide pharmaceutical op committee, and we did
22 have responsibility -- in fact, the ultimate
23 responsibility for the marketing of the drugs both by
24 Fujisawa GMBH and even by Fujisawa Limited in Japan.
25 It wasn't under my supervision, but I was part of the

1 top committee that considered all of those issues.

2 Q. So, are you saying now that you did have sales
3 responsibility?

4 A. I didn't say that.

5 Q. So, you didn't.

6 A. It was not under my supervision. I don't know
7 what you mean by "responsibility."

8 Q. You don't?

9 A. I was part of the committee that did have
10 responsibility. I personally didn't have the
11 autonomous responsibility over that. I don't want to
12 misrepresent that.

13 Q. Let me go back to the deposition on page 87.
14 Have you got that, sir? That's where I asked you the
15 question at your deposition:

16 "QUESTION: But let me just add Abbott and
17 Fujisawa, in either of those jobs, did you have any
18 sales responsibility for products outside of North
19 America?

20 "ANSWER: I had no sales responsibility at
21 either Abbott or Fujisawa outside of North America."

22 Did you give that testimony, sir?

23 A. Yes, I did.

24 Q. It was true at the time you gave it?

25 A. Yes, it was.

1 Q. Has Mr. Audibert had sales responsibility at
2 Schering for products outside of North America?

3 A. I don't -- I don't know that. I don't think
4 so. I mean, it depends on whether -- you know, the
5 marketing and sales are -- are different functions, as
6 you know, and I don't know if he ever headed a sales
7 force.

8 Q. Well, all right, he had marketing
9 responsibility at Schering for products outside North
10 America, did he not?

11 A. I -- as I said, I don't -- I don't believe
12 that -- that he was the individual or that even his
13 department was the individual with marketing
14 responsibility for the -- you know, for behavior in
15 Europe or elsewhere. I think that there were people
16 who were -- there were marketing departments in those
17 respective areas that did that. Now, unfortunately,
18 there is -- there is an ambiguity I think in the names
19 of some of these departments.

20 Q. So, are you disputing that he had sales
21 responsibility -- marketing responsibility for products
22 outside of North America?

23 A. Was he involved in some way with marketing
24 products outside of North America, I can't say. Was it
25 under his supervision, was it under his aegis, I don't

1 think so.

2 Q. Well, you did read his deposition, did you not?

3 A. Yes, I did.

4 Q. And did you see there that he said that he did?

5 A. I'm answering the question -- you asked me; you
6 didn't ask me to parrot what he said.

7 Q. And now I'm asking you whether you read in his
8 deposition that he said that he did.

9 A. I don't recall that.

10 Q. You don't have any basis for disputing it if he
11 did say that, do you?

12 A. I don't have any basis for disputing what he
13 said. I am -- I am trying to answer your question
14 honestly, and I believe that the way the company -- as
15 I understand its organization, he did not have the
16 responsibility for marketing.

17 Q. Okay, but you, sir, you didn't have any
18 responsibility for negotiating licensing deals at
19 Abbott, did you?

20 A. Yes, I did. Again, by the same type of
21 response, you know, I told you, I didn't do it, but I
22 sat on the oversight committee that reviewed those.
23 So, did I negotiate the deals, no. Was I involved with
24 that, yes. And I don't know how to answer your
25 question honestly to -- to include both those

1 situations.

2 Q. Well, let's take a look at your deposition on
3 page 237. It says there, sir, I'll just read your
4 answer:

5 "ANSWER: Yes, because when I was with either
6 Abbott or Fujisawa -- when I was with Abbott, I was a
7 member of the licensing team and didn't have
8 responsibility for negotiating deals."

9 Do you see that?

10 A. Yes.

11 Q. Well, that was my question, sir, whether you
12 had responsibility at Abbott for negotiating licensing
13 deals. We can have it read back.

14 MR. SILBER: Objection, Your Honor. She's
15 asked this question about three times. I believe he's
16 answered it. His answer I believe was consistent with
17 his deposition testimony, and she keeps going over and
18 over the same questions to try to get him to parrot the
19 words that she's saying.

20 MS. SHORES: Your Honor, he said he didn't have
21 responsibility at Abbott for negotiating licensing
22 deals, that's what he said in his deposition. When I
23 asked him the question, he disagreed with that.

24 JUDGE CHAPPELL: Well, I think that she's
25 confirming what he's saying now. So, I am going to

1 overrule the objection and I am going to have the court
2 reporter read it back, get his answer, and let's move
3 along, Ms. Shores.

4 MR. SILBER: Thank you, Your Honor.

5 MS. SHORES: Thank you, Your Honor.

6 (The record was read as follows:)

7 "QUESTION: Well, that was my question, sir,
8 whether you had responsibility at Abbott for
9 negotiating licensing deals."

10 THE WITNESS: And I think I have to say yes
11 with a qualification.

12 BY MS. SHORES:

13 Q. Well, that's not what you said in your
14 deposition, is it, sir?

15 A. It is apparently -- I did not qualify my answer
16 in my deposition.

17 Q. Now, when you were at Fujisawa, you weren't the
18 person going to the table and negotiating the licensing
19 deals. Is that correct?

20 A. That is correct.

21 Q. And you've never specifically focused on a
22 licensing assignment in Europe. Is that right?

23 A. At Fujisawa?

24 Q. Ever.

25 A. No, that's not.

1 Q. If you could go to page 238, and the question
2 is:

3 "QUESTION: When is the most recent time that
4 you undertook this type of an assignment, finding a
5 licensing partner in Europe?

6 "ANSWER: Oh, in Europe?

7 "QUESTION: Well, let me back up. Have you
8 personally ever undertaken such an assignment in
9 Europe?

10 "ANSWER: I've never specifically focused on a
11 licensing assignment in Europe only."

12 Do you see that, sir?

13 A. Yes.

14 MR. SILBER: Objection, Your Honor. A few
15 questions back, she was asking -- and this was at page
16 237, line 23 -- specifically about his experience at
17 Abbott and Fujisawa. She then goes on and starts
18 asking about the specific question about finding a
19 licensing partner in Europe. His answer at his
20 deposition was to that question relating back to his
21 experience at Abbott and Fujisawa. The pending
22 question was "have you ever." It's a different
23 question that was asked at the deposition. It's an
24 improper attempt to impeach.

25 MS. SHORES: Your Honor, the question here, it

1 says, "Have you personally ever undertaken such an
2 assignment in Europe?" I don't think it's improper
3 impeachment at all.

4 JUDGE CHAPPELL: The objection is overruled.
5 She has the right to ask him directly the question out
6 of the deposition and read his answer. If you want to
7 go into it, you have your chance on redirect.

8 MR. SILBER: Thank you, Your Honor.

9 BY MS. SHORES:

10 Q. And Dr. Levy, you have not had the
11 responsibility for filing a new drug application with
12 the FDA in all reality anywhere, have you?

13 A. Do you want me to answer that previous
14 question, because I don't know if I ever answered that
15 previous question.

16 Q. Well, I think you did. My question was whether
17 you said that in your deposition, and I think you said
18 that you had.

19 A. Oh, okay.

20 Q. Now, my question now is whether you have had
21 responsibility for filing a new drug application with
22 the FDA in all reality anywhere.

23 A. Yes.

24 Q. Turn to page 251. It says there:

25 "QUESTION: How many new drug applications on

1 sustained-release products have you filed in the
2 European Union?

3 "ANSWER: As I said before, I believe, I have
4 not had the responsibility specifically to file new
5 drug applications in all reality anywhere."

6 Do you see that?

7 A. Yes.

8 Q. That's what you said at your deposition, right?

9 A. Yes.

10 Q. And maybe your problem with my question was
11 that I said FDA. Let's just ask about Europe.

12 Have you had specifically the responsibility
13 for filing any applications for approvals of
14 pharmaceutical products in Europe at any time? You
15 personally.

16 A. Yes.

17 Q. And what was that, sir?

18 A. The difficulty here comes in this -- defining
19 this term "responsibility." When I answered it in my
20 deposition, I was referring to the fact that I didn't
21 have to do it with my two hands. I had supervisory
22 responsibility for it.

23 Q. So, you think that the question that was put to
24 you in the deposition was asking whether you had
25 physically --

1 A. Whether I had actually done it with my own
2 hands, and because I have had regulatory affairs under
3 my supervision, I -- I didn't do it. I had to
4 supervise its being done and review it and the like.
5 The same thing is true with the questions you were
6 asking me earlier about, you know, the other issues.

7 Q. All right. Well, moving on, Dr. Levy, you
8 can't speak for what the FDA would have done with a
9 product like Niacor-SR, can you?

10 A. I don't know how to deal with a question like
11 that. Nobody can speak for the FDA but the FDA.

12 Q. I want to touch briefly on your work at
13 CoreTechs. Now, most of CoreTechs' revenue, that's
14 your consulting business, right?

15 A. If you would like to characterize it as that.
16 It's not a consulting business, but I am not going to
17 argue semantics with you.

18 Q. Well, it's your personal business, correct?

19 A. Mine and others, yes.

20 Q. And where are the offices for CoreTechs
21 located, sir?

22 A. There is an office in Champaign-Urbana, and
23 there is -- we share office space in Conway Farms
24 Office Park in Lake Forest.

25 Q. Well, what's the business address for

1 CoreTechs?

2 A. The business address that I give for CoreTechs
3 in dealing with my -- my element, my business in
4 CoreTechs, is 1391 Concord Drive in Lake Forest.

5 Q. And what is your --

6 A. Which is my home.

7 Q. -- personal residence address?

8 A. That's my home.

9 Q. Thank you.

10 Now, most of CoreTechs' revenue is from the
11 development of early stage companies, right?

12 A. Yes.

13 Q. And far more than half of its revenue is from
14 the development of early stage companies, right?

15 A. Right now, yes.

16 Q. And the rest of its revenue is derived from
17 consulting, right?

18 A. No.

19 Q. Well, was it -- was that true at the time your
20 deposition was taken?

21 A. No. I'm sorry, let me -- ask me the question
22 again.

23 Q. The question was whether the rest of CoreTechs'
24 income was derived from consulting.

25 A. No.

1 Q. Turn to page 159 of your deposition. It says
2 there in your deposition that, "CoreTechs does two
3 things. What it spends most of its time on and derives
4 most of its revenue from is the development of early
5 stage companies, and the other part of the revenue of
6 the company involves consulting assignments such as the
7 one I'm involved with now, but usually not in support
8 of litigation, but rather, consulting assignments for
9 typically the investment community looking to evaluate
10 various opportunities."

11 A. Yes.

12 Q. Is that true?

13 A. Yes, it is.

14 Q. Now, you sometimes help your startup clients,
15 your startup company clients value their companies. Is
16 that right?

17 A. Yes.

18 Q. And you do such valuations in various ways, do
19 you not?

20 A. Yes.

21 Q. And the way you do that depends on the company,
22 right?

23 A. Yes.

24 Q. And it depends on the technology, right?

25 A. Yes.

1 Q. And it depends on the nature of the business,
2 correct?

3 A. Yes.

4 Q. In fact, you don't believe in fixed formula
5 being applied to all situations, do you?

6 A. Yes.

7 Q. You don't believe in that, right?

8 A. Yes, I don't believe in that.

9 Q. Okay. And you think that every opportunity is
10 different and the thought process that should be
11 brought to every opportunity is different, correct?

12 A. Yes.

13 Q. Now, do you sometimes do sales forecasts when
14 working with your clients?

15 A. Yes.

16 Q. And is it fair to say that forecasting sales in
17 the future is an imperfect exercise?

18 A. Yes.

19 Q. And that's because sales in the future depend
20 on a number of different variables, don't they?

21 A. Among other things, yes.

22 Q. And is it common for companies to do a number
23 of different scenarios based on different events in the
24 future?

25 A. Yes.

1 MS. SHORES: Your Honor, I can move on. This
2 is a good time for a break, but I'm happy to go on if
3 you would like me to.

4 JUDGE CHAPPELL: I think this is a good
5 breaking point. It's about 12:45. Let's take an hour.
6 We'll recess until 1:45.

7 (Whereupon, at 12:45 p.m., a lunch recess was
8 taken.)

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1 AFTERNOON SESSION

2 (1:45 p.m.)

3 JUDGE CHAPPELL: Back on the record, docket
4 9297.

5 Ms. Shores, you may proceed.

6 MS. SHORES: Your Honor, the next portion of my
7 examination relates to the in camera documents that
8 were discussed during Dr. Levy's direct testimony. I
9 think it's about an hour in length, and I guess I would
10 suggest that the courtroom be cleared.

11 JUDGE CHAPPELL: Okay, at this time the public
12 will need to leave the courtroom. We are going to be
13 conducting an in camera session.

14 (The in camera testimony continued in Volume 9,
15 Part 2, Pages 1968 through 2028, then resumed as
16 follows.)

17 JUDGE CHAPPELL: Thank you, we are now in the
18 public record.

19 BY MS. SHORES:

20 Q. I'm going to switch topics on you, okay?

21 A. Okay.

22 Q. I'm going to put up this chart that you did.
23 It says, "Who was involved?" Do you remember that?

24 A. Yes, I do.

25 Q. And these are the people that you say were

1 involved in the Vasomax, Integrelin and Niacor-SR
2 deals, right?

3 A. Yes, that's what that slide says.

4 Q. And I hope you can see this. If not, we'll get
5 you a hard copy.

6 I'd like to focus your attention on the
7 left-hand column for Vasomax. The first name there is
8 something like Angiuoli. Do you see that?

9 A. Yes.

10 Q. And who is Mr. Angiuoli?

11 A. I really don't recall who most of these people
12 were.

13 Q. Well, so, I take it then you can't tell me what
14 the involvement of these people were in the Vasomax
15 deal. Is that right?

16 A. No, I -- what I asked for -- no, I don't really
17 know. I'm slowly learning.

18 Q. All right. So, for the vast majority at any
19 rate of these people, you don't know what they did in
20 terms of evaluating Vasomax, right?

21 A. That's correct, I don't know what they -- what
22 each specifically did. I don't recall that.

23 Q. And I take it the same would be true for the
24 people under the Integrelin column here. Is that
25 right?

1 A. Yes.

2 Q. For example, do you see here Mr. D'Andrade? Do
3 you see this name here?

4 A. Yes, I do.

5 Q. Do you know who that is?

6 A. Yes, I do, and frankly, I missed it. I went
7 through this and asked for, you know, board chairmen
8 and CEOs and presidents and the like to be eliminated,
9 because I thought that was misleading, because while
10 they would have been involved in it, they shouldn't
11 have been on it. So, the initial iteration of this
12 slide, which I believe you were -- you were probably
13 given, had some very senior executives from Schering,
14 and when I saw that, I asked that they be removed, and
15 I simply missed D'Andrade's name.

16 Q. So, you tried to -- in some iteration of this
17 exhibit, you tried to have removed the senior
18 executives and the board members. Is that right?

19 A. Yes, I did.

20 Q. And that's because board members typically
21 aren't personally involved in evaluating deals, right?

22 A. Somehow or other, I feel there's some element
23 of that question that I don't want to say yes to. I
24 mean, board members are not usually, particularly in a
25 company the size of Schering, the first or second line

1 of individuals involved in licensing deals.

2 Q. Okay. I think you said the other day that you
3 gave some instructions to your colleagues here at the
4 FTC about preparing this chart. Is that right?

5 A. Yes, I did.

6 Q. What instructions were those, sir?

7 A. I had gone through quite extensively all the
8 due diligence documents we had on those drugs,
9 certainly on the Niacor drug as well as on the other
10 two, Vasomax and COR, and I asked that a demonstrative
11 be prepared showing the names of the people that were
12 included on the various documents associated with that
13 due diligence process, and that's how this slide came
14 about.

15 Then I looked at it and tried to see whether it
16 comported with the names of the -- in the documents
17 that I had reviewed, and I also asked them to prepare
18 for me, which they did, a list of all the people
19 that -- really whose names had come forth and who they
20 were so that I could see -- and I have another listing
21 that's not shown here listing all these people and what
22 their titles were and what they did, just to see if
23 this -- if this -- you know, to sanity-check this
24 document, if you would. That's how I eliminated those
25 board members, for instance. I just missed D'Andrade's

1 name.

2 Q. I figured that's what you were trying to do
3 based on the new versions of this I kept getting, but
4 initially, as I understand it, you just had somebody on
5 the FTC -- from the FTC go through and write down the
6 names of the people whose names appeared in the
7 documents?

8 A. That's correct.

9 Q. And you didn't read any testimony of any of
10 these people about their involvement in these deals,
11 did you?

12 A. I don't believe so.

13 Q. And that's because the FTC didn't take the
14 depositions of the people involved in these deals, did
15 they?

16 A. Not to my knowledge.

17 Q. And the people whose names appear on these --
18 in these lists who were deposed, they weren't asked any
19 questions about Integrelin or Vasomax, were they?

20 A. I'm sorry, would you repeat that, please?

21 Q. Sure. The people whose names on this list
22 whose depositions were taken, they weren't asked any
23 questions about Vasomax and Integrelin, were they?

24 A. I'm sorry, I -- I don't recall their having
25 been asked about that.

1 Q. Okay. Now, Dr. Levy, you've testified that
2 Schering's agreement to pay a total of \$60 million over
3 three years represents the highest noncontingent
4 payment in the history of the pharmaceutical industry,
5 haven't you?

6 A. I have said that, yes, up to that time.

7 Q. And you've also testified that it's your belief
8 that Schering was really paying for something other
9 than the rights to the licensed products, right?

10 A. I wasn't -- I was not asked really to opine on
11 that. I was asked to offer an opinion on whether I
12 thought it was reasonable for them to have paid \$60
13 million for what they got in the license. I wasn't
14 asked to opine on their other motives.

15 Q. Okay. You've heard of Bristol-Myers Squibb, I
16 take it?

17 A. Yes, I have.

18 Q. It's a reputable company, isn't it?

19 A. Recently, probably not, but up until a few
20 months ago, they certainly were.

21 Q. And what happened a few months ago?

22 A. They did a deal with a company called ImClone,
23 and ImClone has imploded.

24 Q. And what was the amount of the up-front,
25 noncontingent payment that Bristol made in connection

1 with that, do you know?

2 A. \$200 million.

3 Q. And then what happened is that the FDA denied
4 approval to the drug that they had licensed the rights
5 to, right?

6 A. That's correct.

7 Q. Now, at the same time that Bristol-Myers made
8 the \$200 million noncontingent payment, it also
9 acquired 20 percent of ImClone, the company, didn't it?

10 A. Yes, over a period, but -- that's essentially
11 correct, yes.

12 Q. And how much did it pay for that investment, do
13 you remember?

14 A. I believe they paid about a billion dollars.

15 Q. There was nothing contingent about that
16 investment, was there?

17 A. I believe that some of the -- the payments were
18 indeed tied to some approvals, but I don't recall --
19 you know, I have not -- I don't think any of us have
20 been privy to the agreement itself at this point, been
21 just reading press releases and that kind of stuff, and
22 they have tended to vary as to what was up front and
23 what was dependent upon approvals and filings and the
24 like.

25 Q. Well, at least according to the press reports

1 I've read, and let's see if it's true for you, they
2 made payments totaling a billion dollars in the form of
3 a tender offer, right?

4 A. Yes, they did, and the question is, as I'm sure
5 you're well aware, you know, these matters are now
6 before a variety of courts, I guess.

7 Q. Now, ImClone's stock isn't likely to be worth
8 much at the moment, is it, sir?

9 A. Well, "much" is the operative word there. It's
10 certainly worth less than it was, except to Sam Waksal.

11 Q. Do you have any reason to believe that
12 Bristol-Myers has sold the stock in ImClone?

13 A. I have no idea.

14 Q. And do you think that -- or do you know whether
15 its agreement with ImClone would have permitted it to
16 sell the stock so soon after having purchased it?

17 A. No, they would almost certainly have had a
18 lock-up, and I believe even in some of the press
19 releases I've read, they did have a lock-up.

20 Q. So, the fact that Bristol-Myers -- I'm sorry --
21 yes, that Bristol-Myers acquired stock as part of its
22 deal with ImClone, that didn't turn out to offer any
23 protection to it, did it?

24 A. I can't say, because we, of course, don't know
25 what's going to happen to the -- to ImClone's stock. I

1 mean, in a Centocor deal, a company with which -- with
2 whom you've done a deal or Schering has done a deal,
3 had its stock very, very depressed after some bad news,
4 and now Centocor's stock has turned out to be quite
5 valuable with a marvelous market capitalization. I
6 think that it's probably the hope of a variety of
7 people that ImClone will make a similar recovery. I
8 mean, they own the stock, and they can't take that away
9 from them. Whether this stock is valuable, your guess
10 is as good as mine.

11 Q. Well, isn't it true, sir, that Bristol-Myers
12 had written off most of its investment in ImClone?

13 A. I can't say that. I don't know.

14 Q. I'm going to put up on the ELMO here a Wall
15 Street Journal article. It's dated January 25th, 2002.
16 The title of it is "Bristol-Myers Takes Big Write-Down
17 on ImClone."

18 Do you see that?

19 A. Yes, I do. I was unfortunately here that day
20 or on my way home that day, and I actually didn't see
21 this issue of the Journal.

22 Q. You don't have any reason to disbelieve the
23 fact that they did that, do you?

24 A. No, of course not.

25 Q. I'm going to turn to another non-Schering deal

1 involving Eli Lilly. You've heard of them?

2 A. Yes, of course.

3 Q. Is that a reputable company?

4 A. Yes, it is.

5 Q. Are you aware that it paid Icos \$75 million up
6 front to share 50 percent of the profits for a drug to
7 treat impotence?

8 A. I know a fair amount about that deal, actually,
9 because I know the company and I know George Rathman
10 very, very well, and that was indeed the capitalization
11 of a joint venture between the parties, and the \$75
12 million was paid into an LLC joint venture specifically
13 for the purpose of developing this drug. So, I don't
14 think it's fair to characterize it as a payment to Icos
15 in this regard. It was paid specifically to an LLC
16 formed up between the two companies.

17 Q. Okay, let's take a look at this. This is --
18 it's SPX 872. I don't believe that you have it. Let's
19 see if I can get a copy for you.

20 A. I see it, I can read it.

21 Q. You can see that okay?

22 A. Yes, I can.

23 Q. And this is from something, to zoom in on
24 bottom there, called Windhover.com. Have you ever
25 heard of that?

1 A. Sure.

2 Q. What is that?

3 A. It's one of these companies that tries to
4 provide summaries of deals.

5 Q. Okay. Let me see if we can get focused on
6 this. I don't know if we can or not.

7 It says there, "Lilly will pay Icos (uf) \$75
8 million up front to share 50-50 North American and
9 European profits from the sale of Icos' Phase II oral
10 anti-impotence drug IC351."

11 Do you see that?

12 A. Yes, I do.

13 Q. It says, "Lilly has also agreed to pay Icos an
14 added \$52.5 million to form a JV to develop the
15 compound."

16 Do you see that?

17 A. I see that.

18 Q. So, does that not indicate that there was two
19 payments, one, \$75 million up front?

20 A. The only thing I can see here, Ms. Shores, is
21 Windhover is -- the Windhover probably in this
22 particular instance knows a bit less about this deal
23 than I do, and they're just not accurate.

24 Q. Okay. So, you think this is wrong?

25 A. It's -- "wrong" is an awfully unkind word.

1 It's -- it doesn't have quite the slant on the deal.
2 This was a very unusual deal. It was -- it was
3 generated because Bill Gates is on the board of Icos.
4 There's a whole complex thing, which if you would like
5 me to go into a litany on it, I'd be happy to, but I
6 don't think you do.

7 Q. No, I definitely do not.

8 A. But that is not accurate.

9 Q. Why don't we move on to another deal, and
10 that's a deal involving Pfizer and Searle. Are you
11 aware of any such deal?

12 A. Sure.

13 Q. And what was that for?

14 A. For Celebrex.

15 Q. And what's that?

16 A. The blockbuster drug now that's a so-called
17 COX-2 inhibitor used to treat inflammation,
18 particularly osteoarthritis, one of the biggest selling
19 drugs in the world.

20 Q. And how much did Pfizer pay Searle for the
21 rights to co-promote that drug in the United States?

22 A. Yeah, I'm not totally clear on the terms of
23 that. I believe it was \$85 million.

24 Q. So, let's go to Procter & Gamble. You have
25 heard of them, right?

1 A. Yes.

2 Q. And you're aware, then, sir that they did a
3 deal with an entity called Regeneron?

4 A. Yes.

5 Q. That was in May of 1997?

6 A. Yes.

7 Q. And how much did Procter & Gamble pay
8 Regeneron?

9 A. I'm aware of that deal, and some of the -- you
10 know, some of these things are sort of getting fuzzy in
11 my mind. I -- correct me if I'm wrong, as I'm sure you
12 will, but I believe that that was -- I think that that
13 was largely an equity deal, if I'm not mistaken, but I
14 may be wrong about that. I just -- perhaps you could
15 give me -- jog my memory a bit and I can speak of it.

16 Q. Well, I think you're right about that. It was
17 a stock purchase.

18 A. Right.

19 Q. And how much of an investment was it, do you
20 know?

21 A. I don't remember. It was a large -- it was a
22 large investment in Regeneron, and I actually, you
23 know, candidly, in anticipation of your asking me about
24 some of these things, I looked up the stock price of
25 Regeneron then and now, and Regeneron's stock has

1 doubled. So, they did all right on that deal.

2 Q. Well, what was it -- what was it at the time
3 that they did it?

4 A. I've forgotten. I have it written down on the
5 crib sheets you didn't want me to have, as a matter of
6 fact.

7 Q. Does \$60 million sound about right?

8 A. I believe it was \$60 million in equity that
9 they bought, yes.

10 MS. SHORES: Your Honor, I'm at another
11 breaking point if it suits the Court, and I probably
12 have about a half an hour left.

13 JUDGE CHAPPELL: Okay, why don't we -- let's
14 take a break for about 15 minutes. We are in recess
15 until 3:55.

16 (A brief recess was taken.)

17 JUDGE CHAPPELL: Back on the record, docket
18 9297.

19 You may proceed, Ms. Shores.

20 MS. SHORES: Thank you, Your Honor.

21 BY MS. SHORES:

22 Q. Dr. Levy, I want to go back to Niacor for a
23 little bit.

24 A. Okay.

25 Q. Now, you say that another reason anybody

1 considering in-licensing Niacor would have rejected the
2 drug was because of the flushing that it had associated
3 with it, right?

4 A. I don't -- that was certainly another one of
5 its problems.

6 Q. And in your opinion, the incidence and severity
7 of the flushing associated with Niacor-SR would have
8 prevented most patients from using Niacor-SR. Is that
9 right?

10 A. The -- the drug had less flushing than -- than
11 the parent, than niacin, but it still had an 87 or 88
12 percent incidence of flushing, and I thought that was
13 pretty high.

14 Q. And that severity and incidence of flushing,
15 the 88 or 89 percent, in your opinion would have
16 prevented most patients from using the drug, right?

17 A. Not by itself, but again, you know, any
18 prescribing decision is a risk-benefit situation, and
19 had the drug had, you know, some very positive effects,
20 had it not had other side effects, had it done various
21 good things, then sometimes, you know, patients
22 tolerate very difficult things. If there are -- if
23 there are alternatives, then they would not do it.

24 So, I mean, it's -- I don't think I can answer
25 that as, you know, as easily as, you know, as saying it

1 would have precluded their using it.

2 Q. If you could turn to page 9 of your expert
3 report.

4 A. Of my expert report, um-hum.

5 Q. Referring you to the -- have you got page 9
6 there, sir?

7 A. Yes, I do.

8 Q. There's a paragraph with a little (c). Do you
9 see that?

10 A. (C), yes.

11 Q. And you say there that the incidence and
12 severity of flushing, while diminished in patients
13 taking Niacor-SR (relative to patients taking
14 immediate-release niacin), was still very high and, in
15 my opinion, still would have prevented most patients
16 from using Niacor-SR.

17 That's what you said in your report, right?

18 A. Yes, and I think that's right.

19 Q. Now, the overall incidence and severity of
20 flushing for Niacor was very similar to that of the Kos
21 product that's on the market today, correct?

22 A. Yes.

23 Q. If you could turn in your booklet there to SPX
24 1205, it's probably in the back.

25 A. Okay.

1 Q. We looked at this document this morning. These
2 are the IMS data. Is that correct?

3 A. Yes, it is.

4 Q. And this morning we were talking about Tricor,
5 right?

6 A. Yes.

7 Q. This IMS data also reflects sales for Niaspan,
8 does it not?

9 A. Yes, it does.

10 Q. Do you see that?

11 A. Yes.

12 Q. And I'd like you to focus on the last column,
13 which is year to date November '01. Do you see that?

14 A. Yes, I do.

15 Q. And according to this IMS data, Kos had sold
16 \$95 million worth of Niaspan in 2001 up through
17 November, correct?

18 A. Yes, that's what these data say.

19 Q. And it's fair to say, isn't it, sir, that it
20 probably sold over \$100 million in the entire year of
21 2001, right?

22 A. Yes.

23 Q. You don't have any doubt that it sold more than
24 \$5 million worth of Niaspan in the month of December,
25 do you?

1 A. No, I said that.

2 Q. It's fair to say a lot of patients bought
3 Niaspan, isn't it?

4 A. Yes.

5 Q. And that's despite the fact that it had the
6 same incidence and severity of flushing that Niacor
7 did, right?

8 A. Yes.

9 Q. By the way, you're aware, sir, are you not,
10 that Kos has launched a combination niacin/statin
11 product? Are you aware of that?

12 A. Yes.

13 Q. Do you know what it's called?

14 A. No, I don't.

15 Q. Well, I believe it's called Advicor, but at any
16 rate, this combination product has lovastatin, right?

17 A. I think there's two of them. One has
18 lovastatin and one has -- oh, gee, I think it's Lescol.

19 Q. Well, whatever statin it is, it's got a statin
20 and the Niaspan together in a single pill. Is that
21 right?

22 A. Yes.

23 Q. Now, you're aware, Dr. Levy, that Schering, at
24 the time it was evaluating the Niaspan opportunity, did
25 some market research. Are you aware of that?

1 A. The Niaspan opportunity?

2 Q. Yes, the Kos product.

3 A. I -- I believe that they -- what I'm hesitating
4 is I -- the only thing that I think I've seen is
5 their -- some telephonic things they did with some of
6 their physician experts. I don't believe I've seen
7 anything where they went out and did a, you know,
8 full-blown market research analysis, anything like
9 that.

10 Q. Okay. Well, I'm going to show you a document,
11 and we'll see whether it's a full-blown market research
12 analysis or not, but it's in your booklet at CX 576.

13 A. CX 576?

14 Q. Right, CX.

15 A. Yes. I have an SPX 576, then I have a CX 557.

16 Q. Okay, well, go to the one -- see what SPX 576
17 is there. No, that's not it.

18 A. No, that's not it.

19 Q. You don't have a CX 576 in there?

20 A. I don't think so. I have a 557.

21 Q. Well, that's my mistake, Dr. Levy. I'll just
22 give you my copy. I'll ask you to read the title of
23 it.

24 A. Okay, thank you.

25 Q. Would you read the title on that document, sir?

1 A. A Qualitative Evaluation of the Opportunity for
2 Niaspan in Multiple Lipid Disorders, Telephone
3 Interviews with Lipid Specialists.

4 Q. Is that the document that you're recalling that
5 you saw?

6 A. Yes, it is.

7 Q. Would you go to page 20708?

8 A. Okay.

9 Q. It says there that the company has conducted
10 Niaspan research among office-based primary care
11 physicians and cardiologists, does it not?

12 A. Yes, it does.

13 Q. And this was done in the spring of 1997. Is
14 that right?

15 A. I'm not sure when this was done, Ms. Shores.
16 This -- this document is labeled April 1997. I don't
17 know when any of this stuff was actually done.

18 Q. But the report from Decker Research Associates
19 was dated April 1997, right?

20 A. Yes, yes.

21 Q. And that's two months before Schering had the
22 opportunity to evaluate Niacor-SR, correct?

23 A. Yes, it is.

24 Q. Again, if you will turn to 20708.

25 A. Okay, I'm there.

1 Q. It says, "This report presents findings from a
2 series of ten one-on-one in-depth interviews with lipid
3 experts."

4 Do you see that?

5 A. Yes, I do.

6 MS. SHORES: If I could approach the witness,
7 Your Honor, and take it back?

8 Your Honor, permission to approach the witness?

9 JUDGE CHAPPELL: Yes, you may.

10 MS. SHORES: Thank you.

11 BY MS. SHORES:

12 Q. Now, shifting a little bit here, one of the
13 things that you said supports your view that Schering's
14 due diligence was so strikingly superficial as to defy
15 description was that none of the individuals with the
16 responsibility for marketing Niacor-SR in Europe was
17 consulted. Is that right?

18 A. That's correct.

19 Q. Now, Mr. Audibert in connection with the
20 Niaspan opportunity, he consulted with the individuals
21 in Europe who would be responsible for selling Niaspan,
22 did he not?

23 A. I believe he had some -- some comment with
24 them. Mr. Audibert was very peripherally involved with
25 the Niaspan evaluation, as I recall, so I really don't

1 know specifically what he did and didn't do on this
2 project. He was not a key player on this project as
3 far as I recall.

4 Q. Well, why don't we turn to CX 544, hopefully
5 you have got that in your binder.

6 A. Yes, I do.

7 Q. Do you see that document, sir?

8 A. Yes, I do.

9 Q. Now, this is a memorandum dated March 14th,
10 1997 to Distribution, right?

11 A. Yes.

12 Q. That's what it says.

13 A. Um-hum.

14 Q. And it says in the first paragraph, "We have
15 been offered the opportunity to promote a sustained
16 release niacin."

17 Do you see that?

18 A. Yes.

19 Q. That's referring to the Kos product, right?

20 A. I believe so, yes.

21 Q. Now, let's turn the page. This indicates that
22 this memo was sent to somebody in Argentina, correct?

23 A. Yes.

24 Q. Australia?

25 A. Yes.

1 Q. Austria?
2 A. Yes.
3 Q. Belgium?
4 A. Yes.
5 Q. Canada?
6 A. Yes.
7 Q. Denmark?
8 A. Yes.
9 Q. Finland?
10 A. Yes.
11 Q. France?
12 A. Yes.
13 Q. Germany?
14 A. Yes.
15 Q. Greece?
16 A. Yes.
17 Q. Italy, Mexico, Netherlands, Portugal, Spain,
18 Sweden, Switzerland and the United Kingdom, correct?
19 A. Yes.
20 Q. Some of those are countries in Europe, right?
21 A. Yes.
22 Q. Let's go back to the first page.
23 Mr. Audibert is asking these individuals to
24 complete the attached questionnaire, correct?
25 A. Yes.

1 Q. And if you will turn to the last page of this
2 exhibit?

3 A. Okay.

4 Q. That's the questionnaire, correct?

5 A. I presume so.

6 Q. Well, it says, "Sustained-Release Niacin
7 Questionnaire," right?

8 A. I think so, yes.

9 Q. And it asked the individual who got it to
10 indicate whether sustained release niacin was sold in
11 his or her country, correct?

12 A. Yes.

13 Q. If yes, Mr. Audibert wants to know whether it's
14 prescription or not, right?

15 A. Um-hum, yes.

16 Q. He wants to know whether it's reimbursed,
17 correct?

18 A. Yes.

19 Q. And then he asks how much the sales are, right?

20 A. Yes.

21 Q. The questionnaire then asks the individual
22 who's responding to indicate whether there's an
23 opportunity for a sustained release niacin product,
24 correct?

25 A. Let's see, yes.

1 Q. And at the end it asks the person responding to
2 indicate what is your level of interest, right?

3 A. Yes.

4 Q. Now, this was apparently sent only a couple of
5 months before Schering was evaluating the Niacor
6 opportunity, right?

7 A. Yes.

8 Q. Well, you're not saying that Mr. Audibert
9 should have sent out this memo a second time, are you?

10 A. Whether he chose to send the memo or not, the
11 answer is yes.

12 Q. You think he should have sent it out again?
13 That's what you're complaining about?

14 A. No, that's not what I'm complaining about at
15 all.

16 Q. Well, you said --

17 A. I mean, this is one contact with these people
18 for one bit of information. This is not the same thing
19 at all. They are two different drugs, two different
20 indications, two different dosages, and they're two
21 years apart, and so -- in terms of when they would be
22 available or potentially available, so I mean this is a
23 contact with these people in Europe. This is not the
24 end all.

25 Q. Well, it's a consultation with the people in

1 Europe responsible for marketing the drugs. That's
2 what it looks like, right?

3 A. Well, it is a -- you can -- it is -- it is a
4 contact with these people asking for some information.
5 It is certainly not what I would consider a very
6 extensive, to use your term, "consultation."

7 Q. Well, I believe that was your term, Dr. Levy.

8 A. Okay.

9 Q. But --

10 A. Okay.

11 Q. All right, I'd like to revisit this chart that
12 you testified about on direct. Do you remember that?

13 A. Yes, I do.

14 Q. I'm going to set one up on the easel over here.
15 That's the same thing, right, sir?

16 A. Yes.

17 Q. Now, the first basis for comparison between
18 Niaspan and Niacor listed in this chart is therapeutic
19 efficacy, correct?

20 A. Yes.

21 Q. And you admit that the two products are
22 essentially the same in terms of therapeutic efficacy,
23 right?

24 A. As you recall, I didn't prepare this chart, and
25 there were some differences between the products for

1 sure, and so this was a chart that another witness
2 prepared from information, and so for the most part,
3 without trying to debate each point with you, which I
4 don't want to do, they're in the ballpark of
5 therapeutic efficacy. I would not have called them
6 therapeutically equivalent.

7 Q. Well, they're essentially the same in terms of
8 therapeutic efficacy, right?

9 A. There were some -- there were some differences
10 between them in their clinical trials that would
11 have -- that have led -- would have led me not to have
12 characterized therapeutic efficacy in a single line
13 like that. I think there were -- there were
14 differences between these products that could have
15 wound up being significant, and I didn't want to
16 belabor this point in my discussion with you the other
17 day about this table.

18 Q. Well, to say that they are equivalent from the
19 perspective of efficacy, you think that's a reasonable
20 statement, do you not?

21 A. No, I don't think it's a reasonable statement.
22 I think that it -- they're close, and it's not
23 something that -- I don't want to be argumentative with
24 you, and I don't want to debate every point with you.
25 You know, if you're going to press me and say are they

1 therapeutically equivalent, the answer I have to say in
2 an accurate fashion is no. If it is for discussion
3 purposes, are they in the same ballpark, yes.

4 Q. I'm going to show you part of your testimony
5 from the other day. If you would like a whole
6 transcript, I'll be happy to provide it, but we will
7 see if it works on the ELMO.

8 A. Fine.

9 Q. I don't have this highlighted. You say there,
10 and I'm starting about four lines down in your answer.
11 "Therapeutic efficacy," do you see that?

12 A. Four lines down?

13 Q. Four lines down in the answer.

14 A. Oh, I'm sorry, yes.

15 Q. There we go.

16 "Therapeutic efficacy, there are some subtle
17 differences between them, but I think that that's fine.
18 I mean, to say that they are equivalent from the
19 perspective of efficacy, again, I think is a reasonable
20 statement."

21 A. Yes, and that's essentially what I just said a
22 moment ago, I mean, at least I meant to say. There are
23 differences between them, but it's not worth debating
24 at this point.

25 Q. Now, going back to this chart, with respect to

1 dosage, you think that Niaspan is superior, right?

2 A. Yes.

3 Q. And I think you said that a once-a-day drug has
4 a big market advantage over a twice-a-day drug. Isn't
5 that what you said?

6 A. Yes.

7 Q. So, that's why you put a plus in the Niaspan
8 column?

9 A. I didn't put the plus, but that's why I agreed
10 with it. That's not my chart, as you well know.

11 Q. Well, whose chart is it?

12 A. I didn't prepare that chart. That was prepared
13 I believe by Mr. -- by Dr. Bresnahan from his
14 understanding of what I wrote, and I'm -- I'm just
15 saying that I didn't prepare that chart, so I don't
16 want to characterize myself as having done that.

17 Q. Okay, but you don't disagree with this --

18 A. I don't disagree with that.

19 Q. Okay.

20 A. I mean, I took some issue with the -- what I
21 think is a bit of an oversimplification in terms of the
22 therapeutic efficacy. That's what I spoke of a moment
23 ago. In terms of the dosage, I think there's a clear
24 advantage of Kos.

25 Q. Did you review the draft protocols that Upsher

1 provided to Schering when it was evaluating Niacor?

2 A. Yes. Well, there -- one protocol was I believe
3 given in total, as I think I testified, and I did look
4 at that. The other was not really reviewable, because
5 all it was was a page or two. I looked at what they
6 gave me, but there was no way to really review that
7 document, because it -- whatever they gave me was a --
8 is very incomplete, just two or three pages, which is
9 hardly a protocol.

10 Q. Well, there were two draft protocols in the
11 Redwells that Mr. Silber showed you the other day,
12 right?

13 A. That's correct.

14 Q. And one of those protocols was designed to test
15 Niacor in a once daily dosage formulation, was it not?

16 A. Yes, that's correct. I don't remember whether
17 that was the -- the full protocol or whether that was
18 this little more than a cover page of a protocol.

19 Q. Okay, let's go on with this chart. Side
20 effects I think we've covered. Let's go to licensed
21 area.

22 A. All right.

23 Q. There, you agree with the plus that's in the
24 column for Niaspan, right?

25 A. Yes.

1 Q. And that's because the Niaspan opportunity was
2 for the United States, and the Niacor opportunity was
3 for outside the United States, Mexico and Canada. Is
4 that right?

5 A. No, I believe the Niaspan opportunity was
6 potentially available worldwide, including the United
7 States, while the Niacor opportunity was not.

8 Q. So, it's your testimony that at the time that
9 Schering was evaluating Niaspan, Kos was willing to
10 give Schering the rights to Niaspan on a worldwide
11 basis?

12 A. I can't say -- I don't want to speculate about
13 what Kos was willing to do and not willing to do. They
14 did not have a licensee for the rest of the world, and
15 they were certainly not a company capable of marketing
16 at that point in the rest of the world, and so I think
17 that it's not an unreasonable assumption that had
18 Schering wished to enter into an agreement that would
19 have given them worldwide rights, it was something that
20 certainly could have been effected.

21 Q. So, if it were to turn out that Kos was not
22 willing to give Schering the rights to Niaspan on a
23 worldwide basis, would you think that would be a plus
24 for Niaspan? Let's just assume that all they could get
25 was rights to Niaspan --

1 A. In the U.S.?

2 Q. -- in the U.S.

3 A. It still would be an advantage. I'd rather
4 have it in the U.S. than Europe.

5 Q. You'd rather have it in the U.S.?

6 A. Yes.

7 Q. As opposed to outside the United States?

8 A. Yes.

9 Q. Now, people in the industry assume that U.S.
10 sales in the cholesterol-lowering market are roughly
11 half of those -- half of worldwide sales, right?

12 A. Yes, roughly.

13 Q. And in 1997, the market for cholesterol-
14 reducing drugs outside the United States, Mexico and
15 Canada was larger than the market for such drugs inside
16 the United States, Mexico and Canada, wasn't it?

17 A. I don't recall that -- that issue. I think,
18 you know, in trying to be responsive to your line of
19 questioning, we're talking about two niacin products
20 here. We're not talking about statins and fibrates and
21 the like.

22 Q. I was asking you about the size of the
23 cholesterol-lowering market.

24 A. And I answered. I don't remember or I don't
25 know the exact distribution of the sales of the total

1 cholesterol-lowering drugs inside and outside the U.S.
2 in 1997. It was roughly half. It may have been a
3 little bit more internationally or vice versa. I just
4 don't recall.

5 Q. Well, but the IMS data that Mr. Audibert had
6 when he was evaluating Niacor-SR indicated that the
7 market outside the United States, Mexico and Canada was
8 about \$4 billion in 1997, right?

9 A. I don't recall that number.

10 Q. If you would turn to SPX 5 in your binder.

11 JUDGE CHAPPELL: Are we through with this
12 exhibit?

13 MS. SHORES: No. Sorry, Your Honor.

14 THE WITNESS: Okay.

15 MS. SHORES: I'm on the licensed area category.

16 THE WITNESS: I'm sorry, SPX 5?

17 BY MS. SHORES:

18 Q. SPX 5. Do you have that, some IMS data?

19 A. Oh, yes, I'm sorry. Yes, I was looking -- yes.

20 Q. Let me zoom in on this, see if we can see it.

21 It says up here, "Total INT Minus
22 Canada/Mexico."

23 Do you see that?

24 A. Yes.

25 Q. And if we look at the last column, I believe

1 that's 1996 data, it shows total market of
2 \$3,976,000,000, right?

3 A. Yes.

4 Q. Does that sound about right?

5 A. Yeah, they're IMS data, I presume -- yes.

6 Q. Now, the information in Upsher-Smith's data
7 package that it had given to Schering indicated that
8 the market, the cholesterol-lowering market, inside the
9 United States was about \$2.6 billion. Isn't that about
10 right?

11 A. No, because I think that I'd want to see the
12 comparable number from IMS before I start agreeing with
13 you about which one is larger.

14 Q. Okay. Well, I wasn't quite asking you to do
15 that. I was asking you to agree with me that in the
16 materials that Upsher provided to Schering, that's what
17 it said.

18 A. I don't recall what number they represented.

19 Q. Okay, if you could turn to CX 1042 in there,
20 it's probably toward the front.

21 A. Okay.

22 JUDGE CHAPPELL: Ms. Shores, the reason I was
23 asking about the exhibit on the easel, how are you
24 referring to that for the record?

25 MS. SHORES: Your Honor, that is what's been

1 marked for identification as CX 1576.

2 JUDGE CHAPPELL: Thank you.

3 BY MS. SHORES:

4 Q. This is the data package that Upsher provided
5 to Schering, right?

6 A. Yes, it is.

7 Q. And if you could turn to the page marked
8 1600104, it's towards the back.

9 A. Okay.

10 Q. According to this document at least, the U.S.
11 cholesterol reducer market in 1996 was about \$2.6
12 billion, right?

13 A. Well, that's -- that's represented in a table
14 from Upsher-Smith. So, according to this -- I can't
15 disagree with -- that's the number that's there.

16 Q. Do you have any reason to believe that this is
17 inaccurate?

18 A. I have no reason to believe it's accurate, you
19 know, I mean it's not -- I mean, I have no idea who did
20 it, where it was derived from. It's just a number that
21 appeared in Upsher-Smith's documentation.

22 Q. Well, do you know, sir, sitting here today what
23 the size of the U.S. market for cholesterol-reducing
24 drugs was in 1996?

25 A. No, I don't.

1 Q. Well, assume with me, then, that it was \$2.6
2 billion and that this is accurate. Are you willing to
3 assume that?

4 A. No, I'm not willing to assume that. I'm
5 willing to do it hypothetically if you're asking me to
6 do that.

7 Q. All right, assume hypothetically it's \$2.6
8 billion.

9 A. Okay.

10 Q. That's less than \$3.9 billion, right?

11 A. Yes, it is.

12 Q. So -- all right, I'll stop there.

13 Let's keep going with the chart. The next
14 category is regulatory approval. Do you see that?

15 A. Yes.

16 Q. And again, the chart is CX 1576 for the record.

17 A. Yes, I do.

18 Q. And there is again a plus in the column for
19 Niaspan. Is that correct?

20 A. Yes.

21 Q. Now, at the time that Schering was in
22 negotiations with Kos for the right to co-market
23 Niaspan, Niaspan hadn't been approved, had it?

24 A. They had -- as I understand it, in March of
25 1997, they had a letter of approvability from the FDA

1 or a letter stating that it had been through the
2 clinical review, which is the big hurdle, and that they
3 were now discussing final labeling. When you get to a
4 point where you're discussing final labeling with the
5 Food and Drug Administration, you're almost there, and
6 so it would have been a reasonable assumption that this
7 drug was going to be approved.

8 Q. But it hadn't been approved yet, had it?

9 A. The formal approval had not come down. That
10 didn't happen until July.

11 Q. In what countries, Dr. Levy, is Niaspan
12 approved for sale today, do you know?

13 A. I believe it's approved for sale in the United
14 Kingdom, but I don't know of any other countries.

15 Q. It's not approved anywhere else in Europe, is
16 it?

17 A. I just don't know that.

18 Q. All right, the next category on CX 1576 is
19 labeled detailing priority, right?

20 A. That's correct.

21 Q. And in that one -- for that category, we've got
22 a plus in the Niacor column, right?

23 A. Yes.

24 Q. So, that's an advantage of Niacor over Niaspan,
25 according to CX 1576, right?

1 A. It's not an advantage of the drug, one drug
2 over the other. It was the advantage of what seemed to
3 be the deal terms that were going to be demanded by the
4 respective companies. It had nothing to do with the
5 drug.

6 Q. Well, it's relevant for purposes of comparing
7 the opportunities, is it not?

8 A. Yes.

9 Q. All right. Now, the last category is
10 noncontingent payment, right?

11 A. Yes.

12 Q. And you said the other day that there's no
13 evidence that an unrestricted, noncontingent payment
14 would have been required were Schering to have gone
15 forward with the deal with Kos, right?

16 A. I don't know if I said exactly that, but I said
17 something like that.

18 Q. If you could turn to CX 557, do you see that
19 document, sir?

20 A. Yes, I do.

21 Q. This is a contact summary prepared by a
22 Schering employee about a telephone call between
23 Schering representatives and Kos representatives,
24 correct?

25 A. I don't -- I think it is, yes. I -- you know,

1 I -- without reading the whole thing, I -- I'm -- if
2 you say it's a telephone log entry, I have no problem
3 accepting that. I just haven't -- I'm not familiar
4 with it.

5 Q. Well, do you know who Dan Bell is?

6 A. I believe so, yes.

7 Q. Who is that?

8 A. He was one of the officials at Upsher-Smith.

9 Q. At Upsher-Smith or at Kos?

10 A. I'm sorry, at Kos. I'm -- yes, at Kos. I
11 believe he was the president or the CEO of Kos. I'm
12 not sure.

13 Q. And Dr. Levy, was this among the 10,000 pages
14 of documents you said you reviewed?

15 A. I believe I have seen this document before.

16 Q. Let's go to the third paragraph in the body.
17 Do you see that, sir? It begins, "After numerous"?

18 A. Yes.

19 Q. It says, "After numerous back-and-forths,
20 Bell --" that's Dan Bell of Kos, right?

21 A. Yes.

22 Q. "-- says Kos would consider our approach only
23 if we came back with a reasonable up-front payment."

24 Do you see that?

25 A. Yes.

1 Q. And that would be to partially compensate for
2 all of the money they have already spent.

3 A. Okay.

4 Q. Do you see that, sir?

5 A. Yes.

6 Q. Well, that would indicate that Mr. Bell of Kos
7 would entertain negotiations only if Schering came back
8 with a reasonable up-front payment. Do you see that?
9 Do you agree with that?

10 A. No, I don't.

11 Q. You don't agree with that?

12 A. I -- I think that the parties are negotiating.
13 Lots of things get said. The fact is they didn't do
14 it. The fact is it didn't happen. And so what -- you
15 know, it's pointless to speculate about what might have
16 happened. It didn't happen. And so when parties are
17 negotiating, they take rather polarizing positions
18 sometimes, and I think that may be what happened here.

19 Q. Well, you're not disagreeing that Mr. Bell was
20 indicating that Kos would want an up-front payment
21 before he would consider Schering's approach, are you?

22 A. I -- that is what that document says, but
23 you're -- you're asking me to -- to characterize this
24 in a different light from that in which I see it.

25 Q. Well, why don't we take a look at Mr. Bell's

1 deposition. Did you read that?

2 A. Yes, I did.

3 Q. This is the deposition taken by complaint
4 counsel, the FTC in this matter, right?

5 A. Yes.

6 Q. And there, Mr. Bell is asked the question:

7 "QUESTION: Was Kos looking for upfront
8 payments?

9 "ANSWER: Yes, we would have expected upfront
10 payments."

11 Do you see that?

12 A. Sure, yes.

13 Q. It certainly suggests Kos was looking for an
14 up-front payment, right?

15 A. As I think I testified earlier, Ms. Shores, the
16 licensor is always looking for an up-front payment.

17 Q. Well, I think you testified before that there
18 was no evidence that an up-front payment would have
19 been required from Schering in connection with the Kos
20 opportunity.

21 A. I can't speculate about that. It didn't
22 happen. And so what would have -- what would have been
23 required is -- is -- is impossible for you or for me to
24 say. Nothing happened. You know, would -- would Kos
25 have loved to have had an enormous up-front payment?

1 I'm sure they would. Would they have gotten it in any
2 reasonable transaction? That's for you to speculate
3 and for me to speculate.

4 Also, it doesn't talk anything about the
5 magnitude of that. If they had asked for a \$1 million
6 payment, I think I testified that those are very
7 common. A \$5 million payment is not uncommon. We
8 didn't really get into the magnitude of that, nor did
9 they.

10 Q. Well, you said the other day, did you not, that
11 you thought that there was testimony that would suggest
12 that no unrestricted, noncontingent payment would have
13 been required for Schering to have indeed gone forward
14 and chosen to license Niaspan, right?

15 A. Yes, the -- yes, I did. That was from other
16 deposition testimony.

17 Q. Well, did you read the deposition of Mukesh
18 Patel?

19 A. Yes, I did.

20 Q. And who is he?

21 A. Oh, goodness, he I believe was the licensing
22 executive.

23 Q. He's a vice president of licensing at Kos, is
24 he not?

25 A. Yes.

1 Q. So, you saw it where he said, this is at page
2 44 of his deposition -- I'm showing you the wrong page.

3 "ANSWER: Above the line, there's an arrow that
4 says, MPP views are. MPP is myself. These are my
5 views as to what would be critical to me from a
6 licensing point of view and them arriving at a
7 cooperation with us, and the three things in my mind
8 are, stock, which is stock, an investment in the
9 company, Kos, upfront, which is upfront payment for
10 rights to our product, and I've written here, big
11 partner, needs to be a named company, a big name
12 company such as Schering-Plough."

13 You read that in his testimony?

14 A. Yes, I did.

15 MS. SHORES: I don't have any further
16 questions, Your Honor.

17 JUDGE CHAPPELL: Does Upsher-Smith have any
18 cross for this witness?

19 MR. CURRAN: We do, Your Honor. I estimate
20 approximately three hours. I naturally defer to Your
21 Honor as to whether I should start now. Ms. Shores did
22 cover a lot of territory that I had anticipated
23 covering, and I -- in all honesty, I could use some
24 time to reformulate my exam, but if you'd prefer I
25 press on, I'm ready to do that.

1 JUDGE CHAPPELL: Let's roll.

2 MR. CURRAN: Okay.

3 CROSS EXAMINATION

4 BY MR. CURRAN:

5 Q. Good afternoon, Dr. Levy.

6 A. Hi, Mr. Curran.

7 Q. I think you know I'm Christopher Curran
8 representing Upsher-Smith.

9 A. Yes.

10 Q. Dr. Levy, I'd like to begin this afternoon by
11 discussing your background. I know it's been covered
12 to some extent already by Mr. Silber and Ms. Shores, so
13 I'm going to try not to recover tread ground.

14 Sir, the other counsel have already covered
15 your impressive academic career, Yale, Columbia, your
16 internship at NIH and your experience in academia at
17 Duke. Sir, my question about those experiences, sir,
18 at the time you left Duke University Medical Center,
19 you were not an expert in the financial valuation of
20 pharmaceuticals for purposes of in-licensing and
21 out-licensing, correct?

22 A. Yes.

23 Q. Okay. I -- your first experience in corporate
24 America was at Abbott Laboratories, correct?

25 A. Yes.

1 Q. And that was in the early 1980s, that's been
2 established, right?

3 A. Yes.

4 Q. And your position there was as head of R&D for
5 pharmaceuticals, correct?

6 A. Yes.

7 Q. And then, sir, from there you became -- let me
8 use the exact language from your expert report -- in
9 1984, you became the -- can you read that, sir?

10 A. Yes, sir.

11 Q. -- you became the chief executive officer of
12 the CoreTechs Corporation, correct?

13 A. Yes.

14 Q. Sir, who was the chief executive officer of
15 CoreTechs before you?

16 A. No one. I started -- I founded the company.

17 Q. Okay. In fact, sir, at that point in time, the
18 company was known as Nelson L. Levy Associates,
19 correct?

20 A. For about the first two or three months until
21 we could get the -- you know, the name changed through
22 the appropriate IRS authorities. So, yes, when we
23 first formed it -- I first formed it.

24 Q. And that was a corporation incorporated by
25 yourself and your wife as secretary, correct?

1 A. Yes -- ah, I don't recall whether she was
2 secretary or not, but it's not unlikely that she was.

3 Q. And sir, that's the company that you're still
4 doing your business through, correct?

5 A. Yes, that's the -- that's the parent company
6 who -- the -- a name change was done fairly -- you
7 know, fairly -- as soon as I could get it done to
8 CoreTechs, as soon as I brought in two partners and we
9 thought up the name, and that happened sometime later
10 in '84.

11 Q. So, you're the only principal of CoreTechs,
12 correct?

13 A. Right now, I am the only principal.

14 Q. And that's the entity that Ms. Shores was -- I
15 think established that your office is in your home,
16 correct?

17 A. My office is in my home -- one of my offices.
18 I mean, I prefer to work out of -- for the last -- and
19 this is misleading. I had back surgery, as you
20 probably know, in June, and so for the last year it's
21 been easier for me to work at home.

22 Q. Sir, the registered address for Nelson L. Levy
23 Associates and CoreTechs Corporation has been your home
24 address since the company was founded --

25 A. That's correct.

1 Q. -- in the 1980s, correct?

2 A. That's correct, um-hum.

3 Q. Sir, after a few years at CoreTechs
4 Corporation, you then became employed by Fujisawa
5 Pharmaceutical Company, correct?

6 A. Yes, sir.

7 Q. And in that position you were the president of
8 Fujisawa for North America, correct?

9 A. That's correct.

10 Q. And I think in your direct testimony and under
11 questioning from Ms. Shores, you've discussed some of
12 the work you did at Fujisawa, correct?

13 A. Yes.

14 Q. Sir, do you recall in your direct examination
15 testifying as to the circumstances under which you left
16 Fujisawa?

17 A. I don't -- I recall something about it, but --

18 Q. All right, let me -- let me attempt to refresh
19 your recollection in that regard. I'm showing you the
20 transcript from the public record for January 31st,
21 2002. This is from your direct testimony. Let me
22 quote it. This is the questioning by Mr. Silber and
23 the answers by you.

24 "QUESTION: Now, you started with Fujisawa in
25 1991 --

1 "ANSWER: '92 -- well, I mean I became a
2 full-time employee in '92.

3 "QUESTION: Okay, thank you. Then at some
4 point, did you return to CoreTechs?

5 "ANSWER: Yes, I did, in --

6 "QUESTION: In what year?

7 "ANSWER: -- roughly mid-1993, I went back to
8 CoreTechs, had an interesting opportunity arise."

9 Did I read that correctly?

10 A. Yes.

11 Q. And was that your testimony on direct?

12 A. Yes.

13 Q. Sir, in fact, you were forced to leave Fujisawa
14 under unpleasant circumstances, correct?

15 A. No.

16 Q. Sir, isn't it true that the parent company in
17 Japan demanded that you dismiss 30 percent of your
18 staff, and you refused to do so, you had a
19 confrontation, and you left under unpleasant
20 circumstances?

21 A. I don't think it was unpleasant circumstances.
22 That's why I said no to your question. I think that we
23 understood each other very well, and we remain friends.
24 I think we -- we have a -- let's just say a difference
25 in culture.

1 Q. Okay. Sir, at your deposition, you provided
2 the following testimony, did you not, and I quote:

3 "QUESTION: Were you asked to leave?

4 "ANSWER: Yes, I was.

5 "QUESTION: You say in your report --

6 "ANSWER: Well -- well, let me qualify that. I
7 was not asked to leave. I was told to do what they
8 told me to do, that is, to lay off another -- I guess
9 it was another 30-some odd percent of the remaining
10 sales force, and I said I would not do that, and I was
11 given the choice of either doing it or leaving, and so
12 I'm not sure how -- it was -- it was a very mutually
13 agreeable endeavor. Unpleasant, however."

14 Was that your testimony at the deposition?

15 A. Yes, it was.

16 Q. Sir, your expert report --

17 A. If I may --

18 Q. -- in this matter --

19 A. If I may, I mean, it was unpleasant for me. I
20 did not want to leave under those circumstances. I
21 would have preferred not to have to fire 30 people, and
22 I would have preferred to stay in the company -- or 30
23 percent of my people. So, it was -- I mean,
24 "unpleasant" in the way you asked me before and
25 "unpleasant" in the way I answered it there were I

1 think different characterizations.

2 Q. So, sir, your direct examination testimony
3 indicating that you left to pursue an "interesting
4 opportunity," that was inaccurate, wasn't it?

5 A. No.

6 Q. Sir, your expert report in this matter didn't
7 refer by name anyway to this company called Zonagen --
8 and do I say that correctly?

9 A. Zonagen? Yes, that's --

10 Q. I'm not sure if it's a soft G or a hard G.
11 Zonagen?

12 A. Zonagen, yes.

13 Q. And there's been considerable testimony,
14 questioning and answering, by you in the course of your
15 direct and cross examination as to Zonagen, correct?

16 A. Yes.

17 Q. In fact, that's the entity that had a licensing
18 deal with Schering-Plough in 1997. Is that correct?

19 A. Yes, it is.

20 Q. And sir, what was the product -- what was the
21 lead product for Zonagen?

22 A. Vasomax.

23 Q. Vasomax. And can you just remind us what that
24 does, sir, or what it was designed to do?

25 A. Yes, it's designed to treat conditions of both

1 male and female sexual impotence.

2 Q. And sir, in 1997, were there high hopes for
3 that product?

4 A. In 19 -- yes.

5 Q. Is Zonagen a publicly traded company?

6 A. Yes, it is.

7 Q. Do you know what its market cap reached in,
8 say, 1997?

9 A. I don't know what its market cap was. I -- I
10 just don't recall the number of shares outstanding. I
11 believe -- I believe we had -- we didn't have too much
12 shares, I think we had about 11 or 12 million shares
13 with a stock price of about \$30-some odd. So --

14 Q. So, roughly half a billion dollars?

15 A. Yeah, something like that.

16 Q. And that was in and around 1997 when the deal
17 with Schering took place?

18 A. Ah, I -- sir, I'm citing figures after I went
19 on the board, and I went on the board after that deal
20 was, you know, was -- I believe I went on the board in
21 '98, if I'm not mistaken, and so that's the time I'm
22 referring to. I don't know what the market cap was
23 when the deal was done.

24 Q. Okay, I'm not attempting to pin you down to a
25 specific stock price at a particular date.

1 A. That's okay.

2 Q. But ballpark --

3 A. Ballpark.

4 Q. -- do you know the stock price reached
5 approximately half a billion dollars, the total market
6 cap?

7 A. I think it was a little bit less than that, but
8 that's -- yes.

9 Q. Now, sir, are you familiar with the product
10 Viagra?

11 A. Yes.

12 Q. I mean professionally.

13 A. Do I have to answer that, sir?

14 Q. Sir, in 1997, was Viagra approved by the U.S.
15 Food and Drug Administration for anything?

16 A. You know, I don't recall when Viagra was
17 approved. I believe it was, but I just don't recall
18 the date of Viagra's approval. It was around that
19 time. If it hadn't been approved, it was certainly --
20 it was a pretty hot topic on the various and sundry
21 talk shows by that time.

22 Q. Now, sir, Vasomax -- am I saying that
23 correctly, Vasomax?

24 A. Long A, Vasomax.

25 Q. Vasomax, Vasomax, thank you.

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1 Vasomax is and was essentially a rival product
2 to Viagra. Isn't that correct?

3 A. Yes.

4 Q. And some of the documentation we saw regarding
5 the Schering licensing transaction with Zonagen
6 compared Vasomax and Viagra, correct?

7 A. I don't recall. I -- yes.

8 Q. Okay. You have a recollection of that?

9 A. Yes, I do. I mean, the reason I'm hesitating
10 is I don't remember whether I've seen it in your
11 documents or Zonagen documents in the past. I've
12 certainly seen those.

13 Q. Okay. Now, sir, Ms. Shores asked you earlier
14 today whether Vasomax had ever received or has yet
15 received approval by the U.S. Food and Drug
16 Administration, and you said no, correct?

17 A. That's correct.

18 Q. And she also asked you if it had received
19 approvals in Europe, and you said no, correct?

20 A. I don't believe it has. I'm not sure about
21 that, but I don't believe so.

22 Q. Do you know if Vasomax has ever been sold
23 anywhere in the world?

24 A. Yes, it has.

25 Q. And where?

1 A. Latin America.

2 Q. Now, how is that possible? Don't you need U.S.
3 Food and Drug Administration approval before you can
4 sell a drug in Latin America?

5 A. No.

6 Q. No? They have their own regulatory scheme, the
7 countries in Latin America?

8 A. Sir, I'm not particularly informed on
9 registering products and selling products in Latin
10 America to that extent. It's a lot easier to get drugs
11 on the market in Latin America, and what the regulatory
12 pathways are, I really don't know. We were doing a lot
13 of clinical trials in Latin America at Zonagen, and the
14 drug was sold, you know, in those countries, and I
15 don't know if they were approved by any regulatory
16 authorities or not.

17 Q. Okay, but you do know that it -- that Vasomax
18 did not have U.S. FDA approval, yet it was still sold
19 outside the U.S.?

20 A. That's correct.

21 Q. In your experience, are there other drugs that
22 have been sold outside the United States but without
23 U.S. Food and Drug Administration approval?

24 A. Yes.

25 Q. And have such drugs been sold in Europe as well

1 as Latin America?

2 A. Yes.

3 Q. How's that possible? How -- is a drug company
4 allowed to sell a product in Europe without U.S. FDA
5 approval?

6 A. Yes.

7 Q. Why?

8 A. They're independent jurisdictions, and often --
9 less so now, but certainly when -- in fact, back in the
10 days when I was at Abbott and probably the whole decade
11 of the nineties, it was much more common to register
12 drugs in Europe because there was a -- more of a -- the
13 regulatory authorities in the European -- in Europe at
14 that time, at least some of them, were easier, and so
15 drugs were sometimes registered in Italy, Spain, France
16 before they were registered here.

17 Q. Okay. So, those countries, just as far as you
18 know, do not have a prerequisite in their requirements
19 that U.S. FDA approval be obtained first.

20 A. That's correct.

21 Q. Sir, do those countries require clinical study
22 data as a prerequisite to approval?

23 A. Yes.

24 Q. All right. So, if you're a pharmaceutical
25 company and you want to sell a product in, say, Italy,

1 you can do clinical studies and get the data and use
2 that to get approval in Italy without getting the U.S.
3 FDA approval, correct?

4 A. Yes.

5 Q. Sir, in 1997, you were not on the board of
6 Zonagen, correct?

7 A. Correct.

8 Q. Subsequently you were on the board, correct?

9 A. Yes.

10 Q. In fact, earlier today you said you were very
11 involved in the company and the only scientist on the
12 board. Is that correct?

13 A. Yes. I was involved with Zonagen in certain
14 ways even before I went on the board, because I
15 actually -- well, let me -- I won't belabor that. I'm
16 sorry, I'm doing more than you asked me. So, yes.

17 Q. And sir, as I'm sure -- as I'm sure is true
18 with all of your board positions, you've tried to --
19 during your service on the Zonagen board, you've tried
20 to maximize shareholder value, correct?

21 A. Yes.

22 Q. And you've tried to exercise your business
23 judgment in a manner conducive to increasing
24 shareholder value, correct?

25 A. Yes.

1 Q. Sir, how has the Zonagen stock fared say since
2 you first went on the board when its market cap was in
3 the ballpark of half a billion dollars?

4 A. Well, it went up for the first period, and then
5 when we got the -- a clinical hold from the brown fat
6 problem, it's fallen, and now more recently, it's --
7 oh, in the last month or two months, it's pretty much
8 tripled. So, it's gone up -- it seems to be back on
9 its way back up.

10 Q. It fell approximately 90 percent of its value,
11 correct?

12 A. I have not thought about that.

13 Q. Does that sound about right?

14 A. Well, it fell from the thirties to below \$2,
15 and so whatever that is.

16 Q. Did Zonagen swindle Schering?

17 A. I don't think so, no. In fact, I would say no.
18 I shouldn't even hesitate on that. The answer is no.

19 Q. Did Schering make a tremendous blunder in going
20 forward with the licensing transaction for Vasomax?

21 A. In retrospect? I can't say. I think that
22 Vasomax still has a very good chance of becoming an
23 approved product. It's going to be -- at the time it
24 was thought that it would be the second product on the
25 market after Viagra. It may not reach that now. And

1 so I think the opportunity is probably, because it's
2 later if nothing else, it's probably less exciting than
3 it was initially, but I think it's still a good
4 opportunity for Schering, and -- yes. I'm sorry, I
5 tend to talk too much, and I apologize for that.

6 Q. Do you think Schering made the right business
7 decision when it went forward with the licensing
8 agreement?

9 A. You're asking me to second-guess from what I
10 know now?

11 Q. Yeah.

12 A. I think at this point it would be tenuous,
13 because as I said, it's two or three years later than
14 they expected. I think they expected the drug to be
15 approved, you know, shortly after the deal was done,
16 and it was not. I think that Schering has been a very
17 loyal partner and a very assiduous partner in staying
18 with Zonagen through this, and I'm sure that they did
19 it for sound business reasons. So, I think that
20 probably speaks for itself. You know, I don't think
21 they were being charitable in hanging around with
22 Zonagen if they didn't think the deal persisted as a
23 decent deal.

24 Q. Now, sir, isn't it true that sometimes when you
25 view an investment with the benefit of hindsight, it's

1 easy to second-guess the decision that was made at that
2 time?

3 A. Yes.

4 Q. Sir, aren't there a lot of risks involved in
5 pharmaceutical industry business decisions?

6 A. Yes.

7 Q. Sir, some of the risks are market risks,
8 correct?

9 A. Yes.

10 Q. Some of the risks are regulatory risks,
11 correct?

12 A. Yes.

13 Q. In fact, you referred to Zonagen being on
14 regulatory hold?

15 A. I think they referred to it as clinical hold,
16 but yes.

17 Q. Clinical hold. Can you explain for Judge
18 Chappell what that means?

19 A. Yes. When a drug has -- when issues of safety
20 have been uncovered in the course of clinical trials,
21 the FDA may ask that all clinical trials be ceased.
22 They sometimes will allow the ongoing trial to
23 continue. Sometimes they don't even want that to
24 continue, but the bottom line is to protect patients
25 and stop further dosing of those patients.

1 Q. And that's something that happened to Zonagen?

2 A. Yes, it is.

3 Q. Did that happen while you were on the board?

4 A. Yes, it did.

5 Q. And that required a stoppage in clinical
6 trials?

7 A. Well, it was --

8 Q. Is that correct?

9 A. -- easier, because we had already completed the
10 clinical trials, and so what it did from a regulatory
11 point of view, until this issue was resolved, they
12 stopped the clinical review. So, the explanation I
13 gave to His Honor a moment ago in this particular case
14 was somewhat moot, because the trials had been
15 completed, and the FDA was in the midst of the clinical
16 review, but because of this brown fat problem, they
17 actually stopped the review in its tracks as well.

18 Also, there were some other trials that we
19 wanted to conduct, and they -- and -- to supplement the
20 information that we had filed with the NDA, and they
21 forbade us to do that.

22 Q. Now, this clinical hold was an unanticipated
23 development from the perspective of Zonagen, correct?

24 A. Oh, yes.

25 Q. And it was a bad thing to happen, right?

1 A. Yes.

2 Q. And sir, shareholders of Zonagen suffered
3 because of that unexpected development, correct?

4 A. Yes.

5 Q. Including shareholders who bought stock during
6 Zonagen's secondary offering in August of 1997,
7 correct?

8 A. Yes.

9 Q. And in that offering, Zonagen raised \$70
10 million, correct?

11 A. Yes.

12 Q. And shortly thereafter, the stock price of
13 Zonagen fell, correct?

14 A. Yes.

15 Q. And those investors, even with the benefit of
16 retrospect and hindsight, made bad investments,
17 correct?

18 A. You mean they had -- they had made a bad
19 investment you mean?

20 Q. Yes.

21 A. Yes, they had.

22 Q. Now, sir, as a member of the board of Zonagen,
23 is one of your responsibilities to sign corporate
24 disclosure filings?

25 A. Yes.

1 Q. And have you -- have you done that for Zonagen?

2 A. I believe I did. I haven't -- I haven't had to
3 do it in a long time, but I don't -- I don't recall
4 what I signed in that regard when I was there.

5 Q. How many terms did you serve on the board of
6 Zonagen?

7 A. I believe two.

8 Q. And they're two-year terms, correct?

9 A. No, I wasn't on the board for two years. I --
10 I believe I was initially appointed to replace one
11 fellow who went off the board, and then I was elected
12 to another term.

13 Q. Okay.

14 A. So, I think I was on the board for something
15 under three years.

16 Q. And do you recall when you went onto the board?

17 A. I really don't, sir, no.

18 Q. Okay. Does 1998 sound about right?

19 A. That's about right, yes.

20 Q. Now, sir, you referred before to having some
21 involvement with Zonagen before joining the board. Is
22 that correct?

23 A. Yes.

24 Q. What was that involvement?

25 A. At a few different points in time. When the

1 initial technology that actually was quite different
2 from what they ultimately developed -- this technology
3 was licensed from Baylor, and what it was -- it sounds
4 a lot different -- was the -- actually a veterinary
5 vaccine to spay dogs and cats biochemically rather than
6 by surgery, and that was what the initial technology
7 was, and I helped the initial founders of the company
8 license that technology from Bonnie Dunbar at Baylor,
9 and so I had a familiarity with the investors and with
10 the company.

11 And then later, they actually asked me if I
12 would be interested in running the company, and I said
13 no, but I recommended Joe Podolski, who is their -- he
14 became their CEO and still is their CEO. So, I've had
15 a -- you know, just a running interest and sort of
16 running friendship with the company for a while.

17 Q. Who was the name of the discoverer of the drug?

18 A. Bonnie -- well, not the discoverer of the drug.
19 The discoverer of the initial technology -- the reason
20 Zonagen is named Zonagen is zona a was zona pellucida,
21 which was part of the ovary in genetics, and so the
22 initial company had as its paradigm injecting a
23 particular protein from the zona pellucida of dogs and
24 cats into dogs and cats to spay them, and that
25 technology was discovered by Bonnie Dunbar at Baylor,

1 and that's what -- that's how Zonagen was formed.

2 It was after that, when we realized that that
3 technology wasn't working, that we went to plan B, and
4 that's when we came upon the idea and the opportunity
5 to develop phentolamine.

6 Q. Now, sir, you've testified that you have signed
7 corporate disclosure statements filed by Zonagen,
8 correct?

9 A. Yes.

10 Q. Okay. What I've put on the ELMO here is a
11 Zonagen, Inc. Form 10-K. Can you see that?

12 A. Yes.

13 Q. Okay.

14 MR. SILBER: Your Honor, I just wanted to --
15 I'm not sure if this is in evidence, if this is an
16 exhibit or what this document is. I don't know if
17 we've seen it before.

18 JUDGE CHAPPELL: Would you provide a copy to
19 Mr. Silber, please?

20 MR. CURRAN: Yes, of course, Your Honor. It
21 will take a moment to dig one up. I had -- maybe I
22 will move for its admission into evidence. If you will
23 bear with me for a moment, Your Honor, I'll get a copy.

24 JUDGE CHAPPELL: Or you can let him review it
25 and determine whether or not there's an objection.

1 MR. CURRAN: Sure, I can give this one to Mr.
2 Silber. It's for the fiscal year 1999, as it indicates
3 on the first page.

4 MR. SILBER: Your Honor, this just appears to
5 be a 10-K that was filed with the SEC, so we have no
6 objection.

7 JUDGE CHAPPELL: Thank you.

8 You may proceed, Mr. Curran.

9 MR. CURRAN: Thank you, Your Honor.

10 BY MR. CURRAN:

11 Q. Now, Dr. Levy, I'd like to ask if you can --
12 can you see the listing of the board of directors
13 toward the back here?

14 A. Yes, I do.

15 Q. And do you see your name listed there?

16 A. I can't make it out too well, but I think I see
17 it, yes.

18 Q. Nelson L. Levy, that's you, correct?

19 A. Yeah, I just can't read it too well on the
20 ELMO.

21 JUDGE CHAPPELL: You might want to zoom in on
22 it somewhat if you're going to ask him about it.

23 MR. CURRAN: All right, thank you.

24 THE WITNESS: Yes, I see it. I'm sorry.

25 BY MR. CURRAN:

1 Q. Now -- it's my inability to focus this thing.

2 MR. SILBER: Excuse me, Your Honor, I'm just --
3 what he's showing I think is part of an annual report,
4 which it is not clear if it's part of this SEC filing
5 or not. I don't know if this is a separate document.

6 MR. CURRAN: The 10-K is part of the Zonagen
7 annual report, so you can treat it as one document or a
8 separate document.

9 MR. SILBER: So, you are representing that this
10 was filed as part of this document?

11 MR. CURRAN: Yes.

12 MR. SILBER: Okay, withdraw the objection.

13 JUDGE CHAPPELL: Okay, you may proceed.

14 MR. CURRAN: Your Honor, at the conclusion of
15 the day, I will have this marked for identification
16 purposes.

17 JUDGE CHAPPELL: All right.

18 BY MR. CURRAN:

19 Q. Dr. Levy, I'd like to direct your attention to
20 certain passages within the Zonagen annual report, and
21 for this purpose I think it might be better if I
22 provided you with a copy.

23 May I approach the witness, Your Honor?

24 JUDGE CHAPPELL: Yes, you may.

25 THE WITNESS: What page is this on, sir?

1 BY MR. CURRAN:

2 Q. It's page number 12 at the bottom, Dr. Levy.

3 A. Okay.

4 Q. And I'd like to focus your attention in
5 particular on the second full paragraph on that page.

6 A. The one that starts, "One of the Company's"?

7 Q. That's correct.

8 A. Okay.

9 Q. And I'll read that aloud. Sir, do you see
10 where it says, "One of the Company's issued U.S.
11 patents relating to Vasomax is a method-of-use patent
12 rather than a composition-of-matter or formulations
13 patent"?

14 A. Yes, I see that.

15 Q. I am going to continue to read. "A
16 method-of-use patent encompasses the use of a
17 composition to treat a specified condition but does not
18 encompass the composition or formulations themselves.
19 A method-of-use patent may provide less protection than
20 a composition-of-matter patent if other companies
21 market the composition for purposes other than that
22 encompassed by the method-of-use patent, because of the
23 possibility of 'off-label' use of the composition."

24 A. Yes.

25 Q. Okay. And then, sir, farther down on the same

1 page, there's a further passage I'd like to bring to
2 your attention. At the very bottom of the page, where
3 it states, "There can be no assurance that the
4 manufacture, use or sale of the Company's product
5 candidates will not infringe patent rights of others.
6 The Company may be unable to avoid infringement of
7 those patents and may be required to seek a license,
8 defend an infringement action or challenge the validity
9 of the patents in court. There can be no assurance
10 that a license will be available to the Company on
11 terms and conditions acceptable to the Company, if at
12 all, or that the Company will prevail in any patent
13 litigation. Patent litigation is costly and
14 time-consuming, and there can be no assurance that the
15 Company will have sufficient resources to bring such
16 litigation to a successful conclusion. If the Company
17 does not obtain a license under such patents, or is
18 found liable for infringement, or is not able to have
19 such patents declared invalid, the Company may be
20 liable for significant money damages, may encounter
21 significant delays in bringing products to market or
22 may be precluded from participating in the manufacture,
23 use or sale of products or methods of treatment
24 requiring such licenses. The Company does not believe
25 that the commercialization of its products will

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1 infringe on the patent rights of others. However,
2 there can be no assurance that the Company has
3 identified all U.S. and foreign patents that pose a
4 risk of infringement."

5 Sir, did you review that before you signed this
6 10-K?

7 A. You know, as a board member, I was of course
8 asked to review the 10-K, and I'm sure I read that as I
9 did the rest of this document.

10 Q. Okay. Sir, do you agree with the statement
11 that patent litigation is costly and time-consuming?

12 A. Yes.

13 Q. Is that based on personal experience?

14 A. Fortunately -- well, I have known of, but
15 fortunately not as a participant with any of my own,
16 you know, personal enterprises, patent infringement
17 litigation. I certainly know about them.

18 Q. Do you agree with the statement that there can
19 be no assurance that a license will be available to the
20 company on terms and conditions acceptable to the
21 company?

22 A. Yes.

23 Q. What does that expression mean?

24 A. What does what expression mean?

25 Q. The expression I just read, that --

1 MR. SILBER: Objection, Your Honor. I am not
2 clear how this testimony is related in any way to Dr.
3 Levy's direct testimony. This appears to be beyond the
4 scope of cross to me.

5 JUDGE CHAPPELL: You mean beyond the scope of
6 direct?

7 MR. SILBER: Yes, Your Honor, I apologize.

8 JUDGE CHAPPELL: Any response, Mr. Curran?

9 MR. CURRAN: Simply, Your Honor, that I'm
10 probing Mr. or Dr. Levy's experience in a company that
11 he has identified for the first time in his direct
12 examination and a company that was not identified in
13 his expert report.

14 JUDGE CHAPPELL: I'm going to overrule the
15 objection. I'm going to allow this line of questioning
16 for impeachment, just for impeachment purposes. Is
17 that clear?

18 MR. CURRAN: Very good, Your Honor.

19 JUDGE CHAPPELL: You may proceed.

20 MR. SILBER: Your Honor, if I may just raise
21 one other point. I believe on the first day of trial
22 when cross began and there were some exhibits that were
23 introduced and then admitted, you had requested that
24 the parties provide notice to the other party of
25 documents which they would seek to admit on cross

1 examination, and this is the first I think we've seen
2 this document, certainly not marked as a USX, and I
3 think this is the type of document that should have
4 been provided to us ahead of time so that we could have
5 looked at it and determined whether or not it should or
6 should not be admitted.

7 MR. CURRAN: Your Honor --

8 JUDGE CHAPPELL: I think you're right that a
9 public document like a 10-K would fall under that
10 category; however, I did say that if there is a
11 strategic or tactical purpose for not giving you the
12 document, then they don't need to do it ahead of time.
13 So, I think -- I think that everybody understands what
14 the rules are. Is that clear?

15 And I think Mr. Curran was going to tell me
16 that he had some strategic reason not to hand you the
17 10-K, which is developing at this time. Is that right,
18 Mr. Curran?

19 MR. CURRAN: That's very accurate, Your Honor.
20 The reality is, I didn't anticipate using this document
21 until I heard Dr. Levy's testimony earlier today.
22 That's the strategic reason for raising it for the
23 first time now.

24 JUDGE CHAPPELL: Okay, thank you, but you are
25 providing nonstrategic exhibits to opposing counsel,

1 are you not?

2 MR. CURRAN: Yes. Yes, in fact, Your Honor,
3 one principal case in point would be when I did the
4 examination on Friday of the gentleman from Andrx,
5 before that examination even began, I provided the
6 entire binder of cross examination materials to Ms.
7 Bokat.

8 JUDGE CHAPPELL: You may proceed.

9 MR. CURRAN: Thank you, Your Honor.

10 THE WITNESS: So, would you mind repeating the
11 question?

12 BY MR. CURRAN:

13 Q. Of course.

14 My question is simply, and you can refer to the
15 document again, page 12 if you need to, it's simply, do
16 you agree that there can be no assurance that a company
17 will have sufficient resources to bring patent
18 litigation to a successful conclusion?

19 A. Yes.

20 Q. And do you agree that, at least in certain
21 circumstances, there can be no assurance that a license
22 will be available to a company on terms and conditions
23 acceptable to the company?

24 A. Yes.

25 Q. And do you also agree that there can be no

1 assurance that a company will prevail in patent
2 litigation?

3 A. Yes.

4 Q. Sir, Vasomax has a dosage advantage, a dosing
5 advantage, over Viagra, doesn't it?

6 A. It's a pharmacokinetic advantage, you know, I'm
7 sort of splitting hairs with you here. It's not a
8 question of how much of the drug is given or what the
9 dosing schedule is; it's the fact that it has a faster
10 onset of action. So, I'm not sure that that's what I
11 would call a dosing advantage.

12 Q. Well, would it be materially misstating things
13 to say that Vasomax had a dosing advantage over Viagra?

14 A. Yes, I don't think that's what I would --
15 that's not the adjective that I would use in terms of
16 saying a dosing advantage, because that to me implies
17 something different from -- it has an onset of action
18 advantage or, you know, the general term would be a
19 pharmacokinetic advantage.

20 Q. Does it -- would it help if I called it a lead
21 time, lead-in time?

22 A. Yeah, that's fine. I mean, the onset of
23 action.

24 Q. Lead-in time, the onset of action?

25 A. That's the advantage. It acts in -- well, 15

1 to 30, 40 minutes as opposed to Viagra, which is at
2 least 30 minutes and usually an hour to two hours,
3 sometimes even more.

4 Q. So, Vasomax acts in roughly half the time
5 Viagra does, correct?

6 A. Yes.

7 Q. But -- and that was known in 1997, correct?

8 A. Yes.

9 Q. Nonetheless, Viagra is a big hit on the
10 marketplace today, isn't it?

11 A. Yes.

12 Q. Do you know what its annual revenues were for,
13 say, the year 2001?

14 A. No, I don't.

15 Q. Do you have any ballpark?

16 A. Yeah, it's actually been a little bit
17 disappointing, so I -- it's under a billion, I believe,
18 surprisingly. I mean, it looked like it was going to
19 be a -- you know, a \$3, \$4, \$5 billion drug, and it's
20 not managed to do that, but it's certainly a very big
21 drug.

22 Q. What were the annual revenues for Vasomax last
23 year?

24 A. Oh, I don't know, but, you know, trivial. I
25 mean, you know, it's being sold -- I don't even think

1 it's being -- I really don't know, sir, whether it's
2 even -- if it's still being sold in Latin America. I
3 would suspect not because of political hold and that
4 kind of stuff.

5 Q. So, the revenues for Vasomax might be zero for
6 last year, correct?

7 A. Yes, unless they were able to earn some
8 milestone payments from Schering, which I don't think
9 also would have been operative. I -- you asked me a
10 question the answer to which I really don't know.
11 There were a number of opportunities for revenues for
12 the company other than selling the product in the
13 marketplace.

14 Q. But now, sir, you do know that Viagra sold
15 hundreds of millions of dollars last year, correct?

16 A. Yes, certainly.

17 Q. And you do know that Vasomax sold trivial
18 amounts last year, correct?

19 A. That's correct.

20 Q. And sir, you've already acknowledged that the
21 lead-in time for Vasomax is approximately half the
22 lead-in time for Viagra, correct?

23 A. Right.

24 Q. And sir, Viagra has certain side effects that
25 Vasomax does not have, correct?

1 A. Yes.

2 Q. Sir, what does vasodilation mean?

3 A. It means -- I'm trying to explain this without
4 using the word "dilation." It causes a blood vessel to
5 increase its diameter. "Vaso" refers to blood vessel
6 and "dilation" refers to increasing diameter.

7 Q. Is that flushing? Let me --

8 A. No, no.

9 Q. Okay, let me ask a different question. Sir, a
10 side effect of Viagra is flushing, correct?

11 A. Viagra in some patients causes some transient
12 flushing.

13 Q. Some transient flushing?

14 A. Yes. I mean, that is one of the things that
15 Viagra -- that Viagra can do.

16 Q. Sir, in fact, Vasomax, when it was being
17 marketed to licensing partners, advertised that it had
18 an advantage over Viagra because Viagra leads to
19 flushing, correct?

20 A. Yes, yes.

21 Q. And sir, it wouldn't surprise you, would it, if
22 the Zonagen annual report for 1998 stated that the most
23 common side effects of Viagra include headache,
24 flushing and dyspepsia?

25 A. No, I would have thought it listed a few more

1 as well, but yes, it does have side effects. I'm not
2 denying that at all.

3 Q. So, sir, there are certain disadvantages to
4 Viagra as compared to Vasomax, correct?

5 A. Oh, yes, absolutely, and vice versa.

6 Q. But nonetheless, Viagra has had a certain level
7 of success on the market and Vasomax has not, correct?

8 A. Yes.

9 MR. CURRAN: Your Honor, I am going to turn to
10 a different subject now. If you're inclined to break
11 for the day, this would be an ample opportunity.

12 JUDGE CHAPPELL: How long is your next line of
13 questioning going to take, Mr. Curran?

14 MR. CURRAN: About 90 minutes.

15 JUDGE CHAPPELL: Okay, I would -- I have a
16 couple matters to deal with before we adjourn today, so
17 why don't we break here, and we'll conclude your cross
18 examination in the morning.

19 MR. CURRAN: Very good, Your Honor. I would
20 anticipate concluding before lunch tomorrow.

21 JUDGE CHAPPELL: Mr. Levy, you're excused until
22 the morning.

23 THE WITNESS: Thank you.

24 JUDGE CHAPPELL: I have a couple matters here I
25 want to clear up.

1 First I want to close the loop on the issue of
2 the deposition testimony of Lawrence Rosenthal.
3 Procedurally, I had Upsher-Smith file a motion to
4 compel complaint counsel to produce that, the prior
5 testimony of Lawrence Rosenthal. I on the record had
6 granted that motion conditionally, considering whether
7 or not Mr. Rosenthal testified.

8 After he testified, I then conducted an in
9 camera review and instructed complaint counsel to
10 provide redacted portions of the deposition transcript
11 to respondents. At the time, I anticipated someone may
12 want to offer some of that testimony in evidence, so I
13 had provisionally granted in camera status under
14 3.45(g). I then vacated that order when no one used or
15 offered any of that testimony.

16 At this point, I see no reason to make that
17 redacted testimony part of the record in this trial.
18 Therefore, I don't need a marked copy attached to the
19 record for identification.

20 Does anyone object to that?

21 MR. NIELDS: No, Your Honor, no objection.

22 MS. BOKAT: No, Your Honor.

23 MR. CURRAN: No objection, Your Honor.

24 JUDGE CHAPPELL: And I think we all know, Mr.
25 Shaftel I think was his name was representing Andrx and

1 Mr. Rosenthal, and if anyone intends to use any of that
2 testimony as evidence in this proceeding, then you need
3 to give Andrx counsel notice pursuant to our scheduling
4 order.

5 The other matter I want to tend to today is a
6 pending emergency motion for leave to allow complaint
7 counsel to depose a Mr. Mike Vlazza, V L A Z Z A. I
8 received late yesterday an opposition by Upsher-Smith.
9 My ruling is as follows:

10 As movant, complaint counsel has the burden of
11 proof on this issue to demonstrate good cause.
12 Pursuant to the scheduling order issued in this case
13 and pursuant to FTC Rule 3.21(c)(2), complaint counsel
14 has not demonstrated good cause. Accordingly, that
15 motion is denied. The subpoena will not be issued for
16 a deposition; however, a subpoena would be issued, if
17 requested, for trial testimony.

18 Any questions on that ruling?

19 MS. BOKAT: No, Your Honor.

20 MR. CURRAN: No, Your Honor.

21 JUDGE CHAPPELL: Okay. With that, we will
22 adjourn for the day, and we will reconvene tomorrow
23 morning at 9:30. Thank you.

24 (Whereupon, at 5:33 p.m., the hearing was
25 adjourned.)

1 C E R T I F I C A T I O N O F R E P O R T E R

2 DOCKET/FILE NUMBER: 9297

3 CASE TITLE: SCHERING-PLOUGH/UPSHER-SMITH

4 DATE: FEBRUARY 5, 2002

5

6 I HEREBY CERTIFY that the transcript contained
7 herein is a full and accurate transcript of the notes
8 taken by me at the hearing on the above cause before
9 the FEDERAL TRADE COMMISSION to the best of my
10 knowledge and belief.

11

12 DATED: 2/6/02

13

14

15

16 SUSANNE BERGLING, RMR

17

18 C E R T I F I C A T I O N O F P R O O F R E A D E R

19

20 I HEREBY CERTIFY that I proofread the
21 transcript for accuracy in spelling, hyphenation,
22 punctuation and format.

23

24

25 DIANE QUADE

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